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APPENDIX IX - A

Total number of pages = 485

Data Collection Forms for Subjects Completing the Study

HTR Study No.: 03-122085-106
Page No.: IV - 223

Data Collection Form 1

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DEMI	DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM								
Visit Code Date		Subject Initials	Subject Screen #:	Study#					
Subject Qualification	07/15/03 mm dd yy	S/M/L F M L	Permanent #:	03-122085-106					

	20		
Gender: Male Female	Age: <u>20</u>	Years	
oes the subject have any of the following at the treatment sites?			
I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	 		IXIIOW
2. Eczema?			
3. Skin Cancer ?			
4. Skin Allergies ? Please specify:			
5. Hives?			
Does the Subject have any of the following (present and past)?			<u> </u>
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.			
2. Hepatitis?			
3. Heart and Vascular Disease?			
4. Liver Disease?	1//		
5. Kidney Disease?	V/		
6. Tuberculosis?			
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]	V		
8. Cancer?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?			
10. Organ transplant?			
11. Any other condition not listed? Please specify:	V		
Is the subject taking any medication? If yes, please specify below:			
III. MEDICATION	No /	Yes	Don't Know
1. Antibiotics, oral or systemic?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3. Heart Medication?			
4. Insulin?			
5. Other?			
Comments:			
			•
Based on the above medical history, the subject is: Qualified or \(\Basel \)	Not qualifie	ed for the	study.
Interviewer's Signature: Date:	07/1	5,0°	3_ yy

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>TV - 22-4</u>

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07,15,03	SIMIL	Permanent #:	03-122085-106

			INCLUSION CRITERIA						
Ch	eck one								
YES/	N)	Subject:						
V/			1. Is 18 through 65 years?						
1/			2. Has signed informed consent?						
3. Is healthy as evidenced by responses on DCF 1?									
V	1		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?						
V			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?						
V			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?						
V			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?						
/			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?						
レ			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?						
V	/		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?						
V			11. Is willing to comply with all study protocol requirements?						
			EXCLUSION CRITERIA						
	heck one								
YES	NO /	N/A	Subject:						
		/	1. Is currently participating in another clinical study at this or any other facility?						
		1	2. Has participated in any type of hand or arm wash study within the past 7 days?						
	1		3. Has cuts, lesions, or other skin disorders on their hands or wrists?						
	V	,	4. Has artificial nails or nail tips?						
	V		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?						
	1		6. Has eczema or psoriasis on their hands or wrists?						
Female	Female	Male	7. Is currently pregnant? ☐ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☐ positive ☐ positive 7/22:03 of ☐						
	\ \ \	,	8. Is currently lactating?						
	V	/	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?						
	1	/	Has another medical condition which in the opinion of the Investigator would preclude participation?						
	V,		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.						
	1 V		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?						
Base	d upon der	matolog	gic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: lified Not Qualified for participation in this study.						
Reas	ons for dis	qualific	ation: Interviewer's Initials/Date: UNB / 07.15.03						
Investi	gator's Sig	nature:	9 Sm Date: 9 1 8 1 03 mm dd yy						

HTR Study No.: 03-122085-106
Page No.: 12-225

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

71.7	TERCURRENT IL	LIVESS / CONCOM	HIAMAI MEDICATIO	IN PORTA	
Visit Code	Date	Subject Initials	Subject Screen #:	Study#	
Test Period	07/24/03 mm dd yy	5/M/L	Permanent #:	03-122085-106	

II. Has subject been ill since to IV. Has subject used any new Based upon the above respon	oral or topical medication uses, the subject is:	n? □Yes (Comple alified □ Not (te below) ((No Qualified to contin	
Reasons for disqualifica	ation:			
TO BE C	COMPLETED IF SUBJ	ECT HAS AN IN	TERCURRENT II	LNESS
Date of Onset:	Date Reported:	•	Date Resolve	d:
Describe condition:				
Was reaction related to treatm Action Taken: □None □ 0	nent? []Not related [] For a continued on study []			
	ion taken (Complete belo	ow) [Hospitalized	l Other (explai	in)
☐ Medicat Additional Comments:				
		COMITANT ME		
				Indication (Reason for Taking)
Additional Comments: Medication	CON	COMITANT ME Start Date	EDICATION Stop Date	Indication
Additional Comments: Medication	CON	COMITANT ME Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication

	•				
T. A. Simon of the state of the	Date:	07 /	24 /	03	
Interviewer's Signature:	1	mm	dd	уу	

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen#	Study #
07 /24 /03 mm dd yy	S, M, L F M L	Permanent #:	03-122085-106

		E	ASELIN	E		
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS			
10-4	10-5	10 ⁻⁶		10 ⁻⁴	10-5	10 ⁻⁶
ThTL	163	24		ThTC	116	11
MR	193	/3		MR	149	14
CFU/mLJ-8X107	Counted by: _6	APUS 17.28,93		CFU/mL1.3x1C	Counted by:	<u> akbi</u> 7. 28.93

LEFT HAND			W	ASH 1 RI		RIGHT I	RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4	
THE	カスア	41	4	ルル	TATE	55	0	
MR	かた	42	7	MR	加亿	32	3	
THR				THE				
CFU/mL 4.2 x 10 4	Counte	ed by : <u><i>All</i></u>	17.28.03	CFU/mL 4:4X104	_ Counted by	: ans	17.28.03	

LEFT HAND			W	ASH 11		RIGHT I	HAND
10-1	10-2	10-3	10-4	10-1	10 ⁻²	10 ⁻³	10 ⁻⁴
ThTC	THIT	91	13	TATE	232	29	1
MIZ	TUTC	86	12	THIC	2804	0 22	ء
TATE	•			THR			
CFU/mL 8.8.X/04	_ Count	ed by : <i>QU</i>	9 17.28.03	CFU/mL 2.6 X 10 4	_ Counted by	: QLB	17.2803
(*11) Did not es	timete d	ue to the	Courtabili	of the plan. a.	KB 7.28.0	9 3	

Calculations by: TNB / 07.29.03 Raw data reviewed by TNB / 08.01.03 Calculations Verified by: T6 / 7.29.03

*10-1 dilution is the sum of 1.0 mL spread across 3 plates.
Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature:	Date: <u>B / B / O 3</u>

Sı											
	ubject Initials	SM	Su	ubject#_				Study No	o. 03-	<u>-122085</u>	-106
								Page No		- 227	
)				ADVER	STE TO	VENTS				, ,	
	`	· · · · · · · · · · · · · · · · · · ·	•			-				•	***************************************
	Symptom / Ev	ent		III Date	Y/N S	Severity	Action Taken	Outcome	eiation- ship	Investig Signature	
1	red bump	ا ممد	7-25-03	\$7/03	N	1.	1	1	4 8	Tim	المراث
	Entry Comment/No	Λ	-00		los	Fores	ones	n Ed	7816		Initials
7	28/03 1101	1 bus	mos c	w S) ^ N	rds			<u> </u>	•	R
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\vdash			40 1	LLUW	U 47	$\sim \infty$	7 	or if	OCCOU	DUFF	
L	Ohec	<u> </u>					V	· · · · · · · · · · · · · · · · · · ·		<u>·l</u>	
F	Symptom / E	vent	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation-	Investi	
 	see ab	•	or date	11 8		3gh	IANUII		ship	Signatur	eiDate
\vdash	Entry Comment/N		, come	<u> </u>	/_	- 0		ll	<u> </u>		Initials
-	Date		-0 L	0 0	^) ,		/		8 PN
H	729-02 Fa	er gri	nto p	ysud	<u>o</u>	an 1	and .	and of	ingg		- Y-A
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L			·								
				,	SAE ¹		Action	Ţ	Relation-		
1				1 .				•		Invoc	inator
	Symptom / E	Event	Onset Date	End Date	Y/N	Severity	Taken	Outcome	ship		igator ire/Date
		Event	Onset Date	End Date		Severity		Outcome	1		
	Symptom / E Entry Date Comment/I		Onset Date	End Date		Severity		Outcome	1		
	Entry Comment/		Onset Date	End Date		Severity		Outcome	1		ire/Date
	Entry Comment/		Onset Date	End Date		Severity		Outcome	1		ire/Date
	Entry Comment/		Onset Date	End Date		Severity		Outcome	1		ire/Date
•	Entry Comment/		Onset Date	End Date		Severity		Outcome	1		ire/Date
	Entry Comment/		Onset Date	End Date		Severity		Outcome	1		ire/Date
	Entry Comment/	Note:			MU		Taken	d by princ	ship	Signatu	Initials
	Entry Date Comment/I	Note:		Outcome	MU:		Taken	d by prince	ship	Signatu	Initials
	Entry Date Comment/I	Note: 7, Relation 1=Mild 1=Definite		Outcome 2=Mod	MU: erate	ST be de	Taken Taken Stermine 3=Sev 3=Pos	d by prince	ship	Signatu	Initials r.
	Entry Date Comment/I Note: Severity Severity: Relationship:	Note: /, Relation 1=Mild 1=Definite	ship and 0	Outcome 2=Mod 2=Prot 2=Rx ~ 2=Res	MU: erate pable	ST be de	etermine 3=Sev 3=Pos 3=Dis	d by prince of the continued states	ship	estigato 4=Unrela	Initials r. ted (specify)

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106 Page No.: 11 - 228

Visit Code	Date	Subject Initials	Subject Screen #: 158	Study#
Follow-up Visit	07/29/03 mm dd yy	S/M/L F M L	Permanent #:	03-122085-106

Date Subject Entered the Study: O7, 15, 03 mm dd yy	Follow-Up Visit Date: <u>07,29,03</u> mm dd yy						
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema						
YES INO If yes, complete below:							
Clinical Observations: (Include date of onset and descriptions/s Four punk would a provided of the control of							
Comments:							
Has the subject had any health related issues since the treatment	procedure?						
☐ YES → NO If yes, complete below	•						
Comments:							
Medical Consultant's Signature:	Date 7,29,03 mm dd yy						

Page No.: IV - 229

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 14-2	Study#
Subject Qualification	07/15/03 mm dd yy	J/L/R F M L	Permanent#:	03-122085-106

Gender:	Male ☐ Female.	Age: <u>24</u>	Years	
Does the	subject have any of the following at the treatment sites?			
I. DER	MATOLOGIC DISORDER	No	Yes	Don't Know
1.	Psoriasis ?			
2.	Eczema?			
3.	Skin Cancer ?		/	
4.	Skin Allergies? Please specify:	VX		
5.	Hives ?			
Does the	Subject have any of the following (present and past)?			
п. отн	IER MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.	1//	•	
2.	Hepatitis ?		· · · · · · · · · · · · · · · · · · ·	
3.	Heart and Vascular Disease?			
4.	Liver Disease ?			
5.	Kidney Disease?	\ \/		
6.	Tuberculosis ?	V,		
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8.	Cancer ?		,	
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?		/	
10.	Organ transplant ?			
11.	Any other condition not listed? Please specify:			
Is the su	bject taking any medication? If yes, please specify below:			
III. ME	DICATION	No /	Yes	Don't Know
1.	Antibiotics, oral or systemic?			
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	17/		
3.	Heart Medication ?			
4.	Insulin ?			
5.	Other ?	V		
Comme	nts:			
Based o	n the above medical history, the subject is: Qualified or	Not qualifi	ed for the	study.
Intervie	wer's Signature: Date:	<u>07/1</u>	5 103	<u>yy</u>
L	The state of the s			

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>W - 230</u>

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	07/15/03	JILIR	Permanent #:	03-122085-106

	INCLUSION CRITERIA						
Ch	eck one						
YES	/ NO	Subject:					
V	<i>y</i>	1. Is 18 through 65 years?					
1/		2. Has signed informed consent?					
V		3. Is healthy as evidenced by responses on DCF 1?					
V	7	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?					
V	1	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?					
V		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?					
1/		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?					
V		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?					
V		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?					
V		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?					
V		11. Is willing to comply with all study protocol requirements?					
		EXCLUSION CRITERIA					
C	heck one						
YES	NO /	N/A Subject:					
	VX	1. Is currently participating in another clinical study at this or any other facility?					
	VV	2. Has participated in any type of hand or arm wash study within the past 7 days?					
		3. Has cuts, lesions, or other skin disorders on their hands or wrists?					
	V	4. Has artificial nails or nail tips?					
	V	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
		6. Has eczema or psoriasis on their hands or wrists?					
Female	Female 1	7. Is currently pregnant? \(\text{Yes} \) \(\text{No} \) \(\text{Of child-bearing potential:} \(\text{Yes} \) \(\text{No} \) \(\text{If of child bearing potential} \(\text{Post-menopausal, year} \) \(\text{If of child bearing potential} \(\text{Post-HCG Test Results:} \) \(\text{negative} \) \(\text{Dossitive} \) \(\text{8. Is currently lactating ?} \)					
		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?					
	V	10. Has another medical condition which in the opinion of the Investigator would preclude participation?					
	V	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.					
	V	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?					
		atologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: Qualified Dot Qualified for participation in this study. Interviewer's Initials/Date: JNB /07.15.03					
)[gator's Signa	1 2 5 1 Date: 019 107					

HTR Study No.: 03-122085-106
Page No.: W -231

Data Collection Form 3

	INTERCURRENT HEINESS/ CONCOMITANT MEDICATION FORW							
Visit Code	Date	Subject Initials	Subject Screen #:	Study#				
Test Period	07/24/03 mm dd yy	J/L/R F M L	Permanent#:	03-122085-106				

I. Is skin on subject's hands ar If no, please indicate con			•				
II. Has subject used non-antibation of no, please explain:							
III. Has subject been ill since th	ne last visit? □Yes (Con	nplete below)	⊕ No				
IV. Has subject used any new o	ral or topical medicatio	n? □Yes (Comple	ete below)				
Based upon the above respons	es, the subject is: 🖽 🔾	nalified Not	Qualified to contin	ue on the study.			
Reasons for disqualificat	tion:						
	·						
TO BE C	OMPLETED IF SUBJ	ECT HAS AN II	NTERCURRENT II	LLNESS			
Date of Onset:	Date Reported	•	Date Resolve	ed:			
Describe condition:							
Was reaction related to treatme Action Taken: None Medication Additional Comments:	ontinued on study	Withdrawn from ow) □Hospitalized	the study	nsulted physician			
	CON	COMITANT ME	EDICATION				
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm/dd/yy	Indication (Reason for Taking)			
		1 1	1 1				
		1 1	/ /				
Comments:							
. Interviewer's Signature	0 11	· r	Date: 07 / 0	24 , 03			

· Interviewer's Signature:	/	0 1		Date:	07/	24	, 03	
interviewer sorghatare.	Ivan	K. H	asses		mm	dd	уу	

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen# 142	Study#	
07 /24 /03 mm dd yy	J/L/R F. M L	Permanent #:	03-122085-106	

		BAS	ELINE		
LEF	LEFT HAND DILUTIONS			HT HAND DILL	JTIONS
10 ⁻⁴	10-5	10 ⁻⁶	10-4	10-5	10-6
TATC	164	15	TNTC	141	15
TNTC	213	19	TNTC	200	22
CFU/mL1.9xIC	Counted by:	INB 107-28-03	CFU/mL1.7 x1	O Counted by:	JNB/07-28-03

LEFT HAND			W	ASH 1		RIGHT	HAND
10 ⁻¹	10-2	10 ⁻³	10-4	10-1	10-2	10-3	10-4
TNTC	TNTC	164	27	TNTC	TNTC	135	23
TNTC	TNTC	129	20	TATC	TNTC	178	15
TNTC				TNTC			
CFU/mL <u>1.9 x 10 5</u>	Count	ted by : <u>JV</u>	B/07.28.03	CFU/mL1.6x105	Counted by	:JNB	107·28·Q3

LEFT HAND			W.	ASH 11		RIGHT	'HAND
10 ⁻¹	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	10-4
TNTC	TNTC	29	5	TNTC	TNTC	33	3
TNTC	TNTC	38	5	TNTC	TNTC	32_	7
TNTC				TNTC			
CFU/mL 3.4x104	Counte	ed by :UNB	107.28:03	CFU/mL-3-3×104	Counted by	: JNB	107-28-03
				3.2×104	TNB 02.00		

3.2x104 JNB 07.29.03

Calculations by: JNB	107-29-03	Raw data reviewed by	aes	18.1.03			
Calculations Verified by:							
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.							
Underlined values are used for calculation of CFU/mL							
TNTC – Too Numerous To Count							

Investigator's Signature:		Date:	0	0	103	-
251	I Mull Y		mm	dd	yý	

Data Collection Form 6

O 1/20 50 FOLLOW-UP VISIT

HTR Study No.: 03-122085-106
Page No.: TY - 233

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Follow-up Visit	07, 15, 03 mm dd yy	J/L/R F M L	Permanent #: 2	03-122085-106

Date Subject Entered the Study: D7, 15, 03 mm dd yy	Follow-Up Visit Date: O7, 29, 03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, of that may be indicative of a skin infection? TYES NO If yes, complete below: Clinical Observations: (Include date of onset and descriptions/set)	
Comments:	
Has the subject had any health related issues since the treatment	procedure?
Comments:	
Medical Consultant's Signature:	Date 7 1 291 0 3 mm dd yy

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: /06	Study#
Subject Qualification	07/15/03 mm dd yy	M/G/B F M L	Permanent#:	03-122085-106

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To Y			
No Y			
No Y			
No Y			
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_			
/			
DSRH/7.15.03			
No Y	/ AC	on't now	
レ			
V			
,			
	SDSP#/7.1	SDS&H/7.15.03 No Yes De Ko	

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: TT - 235

Visit Code	Date	Subject Initials	Subject Screen #: /06	Study#
Subject Qualification	07/15/03 mm dd yy	M/G/B	Permanent#: 3	03-122085-106

			INCLUSION CRITERIA		
Ch	eck one				
YES	N	0	Subject:		
			1. Is 18 through 65 years?		
	1		2. Has signed informed consent?		
	-		3. Is healthy as evidenced by responses on DCF 1?		
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?		
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?		
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?		
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?		
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?		
~			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?		
			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?		
	-		11. Is willing to comply with all study protocol requirements?		
		_	EXCLUSION CRITERIA		
C	Check one		•		
YES	NO	N/A	Subject:		
			Is currently participating in another clinical study at this or any other facility?		
			2. Has participated in any type of hand or arm wash study within the past 7 days?		
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?		
		<u></u>	4. Has artificial nails or nail tips?		
	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?				
	<u> </u>		6. Has eczema or psoriasis on their hands or wrists?		
Female	Female Female Male 7. Is currently pregnant? \(\) Yes \(\) No \(\) Of child-bearing potential: \(\) Yes \(\) No \(\) Surgically Sterile, year \(\) \(\) Post-menopausal, year \(\) If of child bearing potential - β-HCG Test Results: \(\) negative \(\) positive				
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?		
			10. Has another medical condition which in the opinion of the Investigator would preclude participation?		
			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.		
	<u> </u>	<u>t</u>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?		
Based	d upon de	rmatolo Qua			
Reas	ons for dis	qualific	cation: Interviewer's Initials/Date: SCH / 7.15.03		
Investig	gator's Sig	nature:	S K mm ld Date: 9 1 0 1 0 3 mm dd yy		

HTR Study No.: 03-122085-106
Page No.: W-236

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

	TEACOUNCE IN	DIAMON CONCOM	HIMIT MEDICATIO	IN PORTIZ
Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	07/23/03 mm dd yy	M/G/B F M L	Permanent#: 3	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☐Yes ☑No If no, please indicate condition:							
II. Has subject used non-antibation of the subject	-			es □No			
III. Has subject been ill since th	e last visit? □Yes (Cor	nplete below)	₽ Ńo				
IV. Has subject used any new o	ral or topical medication	n? □Yes (Comple	ete below) 🖾 No				
Based upon the above respons Reasons for disqualificat	-			•			
TO BE CO	OMPLETED IF SUBJ	ECT HAS AN II	NTERCURRENT II	LLNESS			
	nt? Not related ontinued on study on taken (Complete below	Possibly related Withdrawn from ow) □Hospitalized	☐ Definitely related the study ☐ Condin ☐ Other (expla	Other (explain)			
	CON	COMITANT ME	EDICATION				
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)			
		1 1	/ /				
		1 1	/ /				
·		1 1	1 1				
Comments:				•			
	1- 1- 0	Т	Date: 07 / 2	13 / 02			

Interviewer's Signature: Betty M. Conover Date: 07 / 23 / 03 mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen#	Study#
07/23/03 mm dd yy	M/G/B F. M L	Permanent#:	03-122085-106

	BASELINE								
LEFT HAND DILUTIONS				RIGHT HAND DILUTIONS					
10-4	10-5	10 ⁻⁶		10 ⁻⁴	10-5	10-6			
TNTC	116_	22		TNTC	132_	13			
TNTC	144_	12		TNTC	155_	18			
CFU/mL <u>/.3</u> ×	Counted by:	JNB 107.25:03		CFU/mL 1.4×	Counted by: J	NB 107.25.03			

LEFT HAND			W.	ASH 1	RIGHT HAND			
10-1	10-2	10 ⁻³	10 ⁻³ 10 ⁻⁴ 10 ⁻¹		10-2	10-3	10-4	
TNTC	TNTC	TNTC	36	TNTC	TNTC	TNTC	63_	
TNTC	TNTC	TNTC	35_	TNTC	TNTC	TNIC	46_	
TNTC				TNTC				
CFU/mL 3.6×105	_ Count	ted by : JNE	3 107·25·03	CFU/mL 5.4x105	Counted by	y:JNB	107-25:03.	

LEFT HAND				RIGHT HAND			
10 ⁻¹	10-2	10-3	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4
TNTC	TNR	TNTC	42	TUTC	TNK	TNIC	40_
TNTC	TNTZ	TNTC	43	TUTC	TUTC	TNTC	46
TNTC		-		TNTC			
CFU/mL 4.2×105	Counted	d by : <i>0</i> 8	0/7.25.03	CFU/mL 4.3×10 ⁵	Counted by	:_ gm	17.25.03

Calculations by: To /7.26.03 Raw data reviewed by Calculations Verified by: NB /07.29.03 *10-1 dilution is the sum of 1.0 mL spread across 3 plates. Underlined values are used for calculation of CFU/mL TNTC — Too Numerous To Count	alb 18.1.03
Investigator's Signature:	Date: / / mm dd yy

	, .		Data	Collec	ction Form	1 5A				
Subject Initials _	MGB	Su	bject#_	3			Study N	o. <u>03</u>	-12208	<u>5-106</u>
•					•		Page No	o.' <u>I</u>	- 239	<u>z</u>
			ADVER	SE E	VENTS					
Summtons / Ex	ont o	nset Date E	nd Date	AE ¹	Severity	Action Taken	Outcome	Relation-	investi Şignatu	
red bump		7/25/03	3/4/02	N		i aken	<u> </u>	4	Signatu	Λ.
Entry Comment/N	Λ .	0 0.0	100		9 0	1	>		3-16-63	Juitiala .
Date Comment	ne.	valley	ave s	<u>u</u>	1000	org	avon	<u> </u>	MO-15	Initials
7/25/03 red	bump	s one i	option		ands		Lures		1000	gh.
94/03 Snas	rds Cl	ear.	NOM	red	<u>icoti</u>	ous	use	<u>o/</u>	· · ·	gu
						**				<u> </u>
	T			SAE ¹		Action		Relation-	Inves	tigator
Symptom / E	vent	Onset Date	End Date	Y/N	Severity	Taken	Outcome	ship		ure/Date
]							-		
Entry Comment/I	Note:	<u>-</u>								Initials
								•		
										
		•		·····		•			·····	
Symptom /	Event	Onset Date	End Date	SAE Y/N	Severity	Action Taken	Outcome	Relation ship		stigator ture/Date
Symptomy						14.10.11			J. 3	
Entry Comment	/Noté:		<u> </u>	1		<u> </u>	<u></u>	<u> </u>	<u> </u>	Initials
2010										·
		- <u>,</u>				· · · · · · · · · · · · · · · · · · ·				
					\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\					
								<u></u>	·····	
Note: Severit		ship and (Outcome 2=Moo			etermine 3=Se	ed by prin	icipal inv	estigat/	or.
Severity: Relationship:	1=Mild 1=Definite		2=Mod 2=Pro				svere ossible		4=Unrel	lated
Action Taken:	1=None		2=Rx		VQ		scontinued	Study		r (specify
Outcome:	1=Resolved	•	2=Res		w/ seque		ngoing	•	4=Deat	

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: II - 239

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/28/03 mm dd yy	M/G/B FML	Permanent#: 3	03-122085-106

07, 15, 03	07,28,03
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
YES INO If yes, complete below:	
Clinical Observations: (Include date of oaset and descriptions/s	
Comments:	•
<u>)</u>	
Has the subject had any health related issues since the treatment	procedure?
☐ YES NO If yes, complete below	
Comments:	
	*
Medical Consultant's Signature:	Date 7 128 103 mm dd yy

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

	Visit Code	Date	Subject Initials	Subject Screen #: 138	Study#
-	Subject Qualification	07/15/03 mm dd yy	L/E/B F M L	Permanent#: 4	03-122085-106

Gender: Male Female A	ge: 18	Years	
Does the subject have any of the following at the treatment sites?			
I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis?	/,	•	
2. Eczema?	V.		
3. Skin Cancer ?	V.		
4. Skin Allergies? Please specify:	V.		
5. Hives?	V		
Does the Subject have any of the following (present and past)?			
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify. Sulfa drugs	/		
2. Hepatitis?			
3. Heart and Vascular Disease?	V/		
4. Liver Disease ?	V/		
5. Kidney Disease?	V		· · · · · · · · · · · · · · · · · · ·
6. Tuberculosis?	1//		
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8. Cancer?	1		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	1//		
10. Organ transplant?			
11. Any other condition not listed? Please specify: depression anxiety		V	
Is the subject taking any medication? If yes, please specify below:	 		<u> </u>
III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic?	VI		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	VI		
3. Heart Medication?	VI		
4. Insulin?		/	
5. Other? Effexor 150mg lyday depression anxiety		V	
Comments: Other meds: Straterra 25 mg Ixday AI	PD O		
Based on the above medical history, the subject is: Qualified or	Not qualifi	ed for the s	tudy.
Interviewer's Signature: Date:	07/	15/0	3
Au Thirty Control of the Control of			

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: <u>W - 241</u>

		INCLUS.	ION / EXCLUSION	FORM	Page No.: _
	Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	Subject Qualification	07/5/03 mm dd yy	L/E/B f m 1	Permanent#:	03-122085-106
		INC	CLUSION CRITERI	A	
one	>				

Che	eck one	,					
YES /	1	Subject:					
V,		1. Is 18 through 65 years?					
	2. Has signed informed consent?						
1/	1.	3. Is healthy as evidenced by responses on DCF 1?					
1/		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?					
1/		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?					
1/		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?					
1/		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?					
V		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?					
V		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?					
V		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?					
1/		11. Is willing to comply with all study protocol requirements?					
/		EXCLUSION CRITERIA					
С	heck one	·					
YES	NO N/A	Subject:					
	VY,	1. Is currently participating in another clinical study at this or any other facility?					
		2. Has participated in any type of hand or arm wash study within the past 7 days?					
		3. Has cuts, lesions, or other skin disorders on their hands or wrists?					
		4. Has artificial nails or nail tips?					
	V	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
	V	6. Has eczema or psoriasis on their hadds or wrists?					
Female	Female, Male	7. Is currently pregnant? ☐ Yes ☑ No Of child-bearing potential: ☑ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☑ negative ☐ positive 7/24/03 € 8. Is currently lactating?					
		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?					
	10. Has another medical condition which in the opinion of the Investigator would preclude participation?						
11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles. 12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?							
Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: Qualified Not Qualifie							
Reas	ons for disqualific						
Investigator's Signature: Ly 2 1 2 1 Date: mm dd vy							

HTR Study No.: 03-122085-106
Page No.: <u>W - 242</u>

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/24/03 mm dd yy	<u>L E B</u> F M L	Permanent #:	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? EYes No If no, please indicate condition:						
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? If no, please explain:						
III. Has subject been ill since the last visit? Yes (Complete below) No						
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	ete below) 🖾 No			
Based upon the above respon	ses, the subject is: 🖳 🛈	ialified Not	Qualified to contin	ue on the study.		
Reasons for disqualifica	ition:					
	·					
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT II	LLNESS		
Date of Onset:	Date Reported	•	Date Resolve	d:		
Describe condition:			•			
Was reaction related to treatme	ent? 🗆 Not related 🔻 🗆 I	Possibly related	☐ Definitely related	☐ Other (explain)		
Action Taken: None	continued on study	Withdrawn from	the study 🔲 Con	nsulted physician		
☐ Medicati	ion taken (Complete belo	ow) []Hospitalize	i 🛘 Other (expla	in)		
Additional Comments:						
	CON	COMITANT MI	EDICATION			
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm/dd/yy	Stop Date mm / dd / yy	Indication (Reason for Taking)		
		1 1	1 1			
		1 1	1 1			
· ·		1 1	1 1			
Comments:						
Interviewer's Signature: Betty M. Conover Date: 07/24/03						

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Test Date Subject Initials Subject Screen f		Study#					
07 /24 /03 mm dd yy	LIEIB F. M. L	Permanent #:	03-122085-106					

		I	ASELIN	VE		
LEFT	HAND DILUT	IONS		RIGH	T HAND DILU	TIONS
10-4	10 ⁻⁵	10 ⁻⁶		10-4	10-5	10-6
TNTC	148	10		TNTC	134	20
TNTC	TNTC 94 14				118	19
CFU/mL1.2x107 Counted by : JNB/07.2803				CFU/mL 1.3 XIO	Counted by:	JNB/07.28.0

LEFT HAND			W	ASH 1	RIGHT HAND			
10 ⁻¹	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4	
ThTC	TUTC	49	4	72.77	THTC	61	4	
TUTC	THIC	53	4	THE	THIC	50	5	
THIC				TUTE		**		
CFU/mL 5.1×104	Count	ed by : _ <i>Q.L</i>	10,2803	CFU/mL 5.6 x 10 4	Counted by	: also	17.28.03	

LEFT HAND		WASH 11				RIGHT	HAND
10 ⁻¹	10-2	10 ⁻³	10-4	10-1	10-2	10-3	10-4
かた	120	10	3	THTL	90	15	3
MC	82	11	1	MR	81	12	4
MR				THR		***	
CFU/mL 1.0 × 10 4	Counte	d by :	17.28.43.	CFU/mL8.6×10 ³	Counted by	y: als	17.28.43

Calculations by:	JNB	107.29.03	Raw data reviewed by _	54S	18-1-03	
		TO 17:	29.03			
*10-1 dilution is t	he sum of 1	.0 mL spread acro	oss 3 plates.			
Underlined values are used for calculation of CFU/mL						
TNTC - Too Numerous To Count						

Investigator's Signature:	Date:	8	8	103	
M. Manull		mm	dd	уу	

S	Subject Initials <u>LEP</u>		ubject #_		VENTS		Study N Page N		-12208 L-37 IV-2	
F	Symptom/Event Reaction to Effexor	Onset Date E		AE'	Severity	Action Taken	Outcome	Relation- ship	Investi Signatur	
3	Entry Date Comment/Note: 6/03 Took 225 mg	ווט	//		xiety	1×de	y f	rom	-160	Initials
	neuroligi	31/03, u	discor <u>oblan</u>	nti us	MULO	ZML		L 40-		
	Symptom / Event	Onset Date		SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship		igator re/Date
	Entry Date Comment/Note:									Initials
. [Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship		tigator ure/Date
-	Entry Date Comment/Note:						·			Initials
	Note: Severity, Relatio Severity: 1=Mild	nship and O	2=Mode	erate	ST be de	etermine 3=Sev		cipal inv	estigato	or.
}	Relationship: 1=Definite Action Taken: 1=None Outcome: 1=Resolve seque	ed w/o		herap	w/ sequela		continued		4=Unrela 4=Other 4=Death	(specify)

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IX - 2445

					_
Visit Code	Date	Subject Initials	Subject Screen #:	Study#	
Follow-up Visit	07/29/03 mm dd yy	LIEIB F M L	Permanent#: #	03-122085-106	

Date Subject Entered the Study:	Follow-Up Visit Date:
07, 15, 03	07, 29, 03
Control Contro	Managharan appropriation and appropriation appropriation and appropriation and appropriation and appropriation and appropriation and appropriation and appropriation appropriation and appropriation and appropriation appropriation appropriation and appropriation appropriation and appropriation appropriation appropriation appropriation appropriation and appropriation appropriation appropriation appropriation appropriation and appropriation appropriation appropriation appropriation appropriation appropriation appropriation appropriation appropriation
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
☐ YES XNO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/s	severity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatmen	at procedure?
YES INO If yes, complete below	
Comments: Drug geortion - G	lhxor.
Medical Consultant's Signature:	Date 7 1291 03
Co Juin tresue.	mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>W - 246</u>

03-122085-106

Years

Data Collection Form 1

Subject

Qualification

☐ Male

Female .

Does the subject have any of the following at the treatment sites?

Gender:

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Permanent #:

Age: <u>65</u>

DEMOGRAFINES/DERMATOLOGICAL/MEDICAL HISTORY FORM				
Visit Code	Date	Subject Initials	Subject Screen #: 102	Study#

I. DERMATOLOGIC DISORDER	No/	Yes	Don't Know
1. Psoriasis?	V/		
2. Eczema?			
3. Skin Cancer ?			
4. Skin Allergies? Please specify:			
5. Hives ?	V		
Does the Subject have any of the following (present and past)?			•
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	//		
2. Hepatitis?			
3. Heart and Vascular Disease?			
4. Liver Disease ?	1/		
5. Kidney Disease ?			
6. Tuberculosis?	V.		1
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8. Cancer?	1		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?		•	
10. Organ transplant?	V		
11. Any other condition not listed? Please specify:			
Is the subject taking any medication? If yes, please specify below: III. MEDICATION	Noz	Yes	Don't
	-		Know
1. Antibiotics, oral or systemic?	1/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	+V/	<u> </u>	
3. Heart Medication?	1		
4. Insulin?	/-		
5. Other?	<u> </u>	<u> </u>	
Comments:			
Based on the above medical history, the subject is:	Not qualifi	ed for the	study.
	07 /	15/0	3
Interviewer's Signature: Date:	mm	dd	уу
Interviewer's Signature: Date:		đđ	уу
Interviewer's Signature: Date:		dd	уу

Data Collection Form 2 INCLUSION / EXCLUSION FORM

Subject Initials

Visit Code

Date

HTR Study No.: 03-122085-106 Page No.: W-247 Subject Screen #: 102 Study# Permanent #:

i		Q	Sub ualifi	ject cation	07/5/03 mm dd yy	LIJIB	Permanent#:	5	03-122085-106	
<u></u>	INCLUSION CRITERIA					<u> </u>				
Ch	eck one									********
YES/	<u>'</u>	0/		Subject:					·	
	/			1. Is 18	through 65 years?					
1	4_	,		2. Has s	signed informed conse	nt?				
V				3. Is he	althy as evidenced by i	responses on DCF 1	?			·
V	X	,		4. Has l	nands and wrists that a	re free of dermatose	s, cuts, lesions, and	other sk	in disorders?	
V	/			5. Has i	fingernails that extend	no longer than appr	oximately one (1) m	m past t	the nail bed?	
V					lling to refrain from us ering, and handwashin			bars) fo	r bathing,	
V				7. Is wi	lling to refrain from us	sing anti-dandruff sl	ampoo during the er	ntire stu	ıdy ?	
V				liqui		dorant/antiperspirar			is, creams, oils, dishwashing study, unless prescribed by	
/					illing to refrain from u sician for an intercurre		during the entire stu	ıdy, unl	ess prescribed by a	
V					illing to refrain from u ss prescribed by a phy			ation di	uring the entire study,	
V				11. Is w	illing to comply with a	all study protocol rec	uirements?			
					EX	CLUSION CRITI	RIA			
C	Check on	e								,
YES	NO	<u>/</u>	V/A	Subject:						
	V	1		1. Is c	urrently participating i	n another clinical st	dy at this or any oth	er facil	ity ?	
	V	1		2. Has	participated in any typ	pe of hand or arm w	sh study within the	past 7 d	lays ?	
	V	\mathcal{T}		3. Has	cuts, lesions, or other	skin disorders on th	eir hands or wrists?			
		,		4. Has	artificial nails or nail	tips?				
	1./	1		5. Has	soap, detergent, antib	iotic, Polysporin® a	nd/or perfume allerg	gies ?		
	V			6. Has	eczema or psoriasis o	n their hands or wri:	ts?		/	
Female	Female	N	⁄[ale		urrently pregnant? ☐	Surgically Sterile, ye		al: Ye ost-meno posi	opausal, year	
	V	1			urrently lactating?	m p 1100 1031166	uno. L. noguero	<u> </u>		
	1	1			s been medically diagn					
	V		,		atitis, an organ transpl thematosus, thyroiditis			DS (or I	HV positive), Lupus	
	V	10. Has another medical condition which in the opinion of the Investigator would preclude participation?								
	V	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.								
	1/			12. Has	s a known sensitivity to	o isopropyl alcohol	r the ingredients in	antibact	terial soaps ?	
Base	d upon d	erma	tolog Qual	ic evaluati ified [on and the information Not Qualified	for participation	in this study.			
Reas	ons for d	isqu	alifica	tion:		Intervie	wer's Initials/Date:_	JNB	107.15.03	
Investi	gator's S	ignat	ure:	L	19 20		Date:	/	<u>0</u> 103	

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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07 /24 / 03 mm dd yy	L/J/B F M L	Permanent #:	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Tes INo If no, please indicate condition:							
•	II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? If no, please explain:						
III. Has subject been ill since	he last visit? Yes (Cor	nplete below)	No No				
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) 🖃 🗸				
Based upon the above responses, the subject is: Equalified Not Qualified to continue on the study. Reasons for disqualification:							
то ве с	COMPLETED IF SUBJ	ECT HAS AN II	NTERCURRENT D	LLNESS			
Date of Onset:	Date Reported	*	Date Resolve	ed:			
Describe condition:							
Was reaction related to treatm Action Taken: □None □ □ Medicat Additional Comments:	Continued on study ion taken (Complete belo	Withdrawn from	the study Con	nsulted physician in)			
	CON	COMITANT MI	EDICATION				
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)			
		1 1	1 1				
	1 1 1 1						
Comments:							
Interviewer's Signature:	m. R. born	; I		24/ 63 dd yy			

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

•	Test Date	Subject Initials	Subject Screen #	Study#	
	07 /24 /03 mm dd yy	L/J/B F. M L	Permanent #: 5	03-122085-106	

	BASELINE						
LEF	T HAND DILUT	IONS	RIG	HT HAND DILU	TIONS		
10 ⁻⁴	10-5	10 ⁻⁶	10-4	10-5	10-6		
TRTC	214	_35	THE	216	23		
THR	222	19	TUTE	182	15		
CFU/mL2.4y/	<u>'0</u> 7Counted by : _	ako 17.28.03	CFU/mL 2.0 X	O Counted by:	QUB17.28.43		

LEFT HAND			W	ASH 1	RIGHT HAND		
10 ⁻¹	10 ⁻²	10 ⁻³	10-4	10-1	10-2	10-3	10-4
THTC	TATE	79	12	カル	TATE	179	16
ME	MR	114	6	TATE	TUTL	131	26
カモ				7.17.			
CFU/mL 9.6×104	Count	ed by : _ <i>Q</i>	10 7.2843	CFU/mL <u>1.8 X 10 ⁵</u>	_ Counted by	: ars	17.28.03

LEFT HAND		WASH 11 RIGHT HAND				HAND	
10-1	10-2	10 ⁻³	10-4	10-1	10 ⁻²	10 ⁻³	10-4
160	94	6	10	nr	175	15	3
161	59	10	0	ThT	107	24	Q
714				Mt			
CFU/mL6.8x103	Counte	ed by : <i>All</i>	17.28.03	CFU/mL/-4×104	Counted by	: arb	17.28.03

Calculations by: JNB /07.29.03 Raw data reviewed by JNB Calculations Verified by: 10.1 /7.29.03 Raw data reviewed by 10.1 dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL 108.01.03

TNTC - Too Numerous To Count

Investigator's Signature:	Date: 8 1 8 1 0 3 mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 250

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/29/03 mm dd yy	L/J/B F M L	Permanent#: 5	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: O7/29/03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatment of YES NO If yes, complete below	t procedure?
Comments:	
Medical Consulant's Signature:	Date 7,29,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: IV -251

03-122085-106

Years

21

Age:

Data Collection Form 1

DEMOCR APHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Subject Qualification

☐ Male

Gender:

mm

Female.

DEAN	JORAL IIICS/DEX	WAT OLOGICAL	MEDICAL MISTOR	1 FORM
Visit Code	Date	Subject Initials	Subject Screen #:	Study#

Permanent #:

1. Psoriasis? 2. Eczema? 3. Skin Cancer? 4. Skin Allergies? Please specify: 5. Hives? Does the Subject have any of the following (present and past)? II. OTHER MEDICAL INFORMATION 1. Allergies.? Please specify. 2. Hepatitis? 3. Heart and Vascular Disease? 4. Liver Disease? 5. Kidney Disease? 6. Tuberculosis? 7. Diabetes? Controlled? Diet[] Oral[] Insulin[] 8. Cancer? 9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)? 10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs? 3. Heart Medication?	Y	es Don't Know
3. Skin Cancer? 4. Skin Allergies? Please specify: 5. Hives? Does the Subject have any of the following (present and past)? II. OTHER MEDICAL INFORMATION 1. Allergies.? Please specify. 2. Hepatitis? 3. Heart and Vascular Disease? 4. Liver Disease? 5. Kidney Disease? 6. Tuberculosis? 7. Diabetes? Controlled? Diet[] Oral[] Insulin[] 8. Cancer? 9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)? 10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	Y	66
4. Skin Allergies? Please specify: 5. Hives? Does the Subject have any of the following (present and past)? II. OTHER MEDICAL INFORMATION 1. Allergies.? Please specify. 2. Hepatitis? 3. Heart and Vascular Disease? 4. Liver Disease? 5. Kidney Disease? 6. Tuberculosis? 7. Diabetes? Controlled? Diet[] Oral[] Insulin[] 8. Cancer? 9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)? 10. Organ transplant? 11. Any other condition not listed? Please specify: III. MEDICATION No 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	Y	66
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7. Diabetes? Controlled? Diet [] Oral [] Insulin [] 8. Cancer? 9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)? 10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
8. Cancer? 9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)? 10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
10. Organ transplant? 11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
11. Any other condition not listed? Please specify: Is the subject taking any medication? If yes, please specify below: III. MEDICATION 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
Is the subject taking any medication? If yes, please specify below: No. 1. Antibiotics, oral or systemic? 2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	<u> </u>	, , , , , , , , , , , , , , , , , , ,
 Antibiotics, oral or systemic? Cortisone, Steroids, ACTH, Anti-reaction Drugs? 		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?	Y	Tes Don't
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?		
	///	
4. Insulin?		
5. Other?		
Comments:		
Based on the above medical history, the subject is: Qualified or Not qu	ialified fo	or the study.
Interviewer's Signature: Jame Busemerk Date: 07 mm	/ 15 dd	/ 03 yy
$\overline{}$	-	

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>TV - 252</u>

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	07,15,03	L,M,P	Permanent#:	03-122085-106

			INCLUSION CRITERIA
	eck one	_	
YES	NO) :	Subject:
<u></u>	4,_		1. Is 18 through 65 years?
	/		2. Has signed informed consent?
/	/		3. Is healthy as evidenced by responses on DCF 1?
	4		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?
V	<u> </u>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?
V	4		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?
V			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?
/			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?
\overline{V}			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?
V			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?
			11. Is willing to comply with all study protocol requirements?
			EXCLUSION CRITERIA
C	heck one		
YES	NO /	N/A	Subject:
		1.	1. Is currently participating in another clinical study at this or any other facility?
			2. Has participated in any type of hand or arm wash study within the past 7 days?
		7	3. Has cuts, lesions, or other skin disorders on their hands or wrists?
			4. Has artificial nails or nail tips?
	1	/	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?
	1		6. Has eczema or psoriasis on their hands or wrists?
Female	Female	Male	7. Is currently pregnant? ☐ Yes W No Of child-bearing potential: ☐ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year If of child bearing potential - β-HCG Test Results: W negative ☐ positive 7/24/03 on
	V	/	8. Is currently lactating?
		/	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?
	1		10. Has another medical condition which in the opinion of the Investigator would preclude participation?
	V	/	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?
Based		matologi D Qual	ic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: ified
Reaso	ons for disc	-	-TA TQ 17.15.172
)	gator's Sign		GN mull Date: B1 8 103 mm dd yy

HTR Study No.: 03-122085-106 Page No.: <u>W -2</u>53

Data Collection Form 3 INTERCURRENT ILLNESS / CONCOMITANT MEDIC

, L. V	TERCURRENT IL	LINESS / CONCOR	HIANT MEDICATIO	N FURM
Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07124103 mm dd yy	<u> </u>	Permanent #:	03-122085-106

I. Is skin on subject's hands as If no, please indicate con									
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? EYes No If no, please explain:									
III. Has subject been ill since the	ne last visit? □Yes (Con	nplete below)	2 No						
IV. Has subject used any new o	oral or topical medication	n? □Yes (Comple	ete below) (100						
Based upon the above respons	ses, the subject is: 🖂 🕻	alified Not	Qualified to contin	nue on the study.					
Reasons for disqualification:									
	·								
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS					
Date of Onset: Date Reported: Date Resolved:									
Describe condition:									
Was reaction related to treatment? ☐Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)									
Action Taken: None Continued on study Withdrawn from the study Consulted physician									
☐ Medication	on taken (Complete belo	w) 🗆 Hospitalized	i 🛘 Other (expla	in) .					
Additional Comments:									
		COMITANT MI							
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)					
		1 1	/ /						
		1 1	1 1						
		1 1	1 1	y					
Comments:			•						
•				24/ . 03					
Interviewer's Signature:	the M. Conon	ا ري	Date: 07 1 2	14/03					

mmdd

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen # 「54	Study#
07 /24 /03 mm dd yy	L/M/P F. M L	Permanent #:	03-122085-106

M	·	BAS	ELINE		
LEFT	HAND DILUTI	ONS	RIG	HT HAND DILU	TIONS
10-4	10 ⁻⁵	10 ⁻⁶	10-4	10-5	10-6
DET	208	24	ThTZ	146	16
MR	190	16	The	124	20
CFU/mL2.0¥/0	Counted by: _C	ABB 17.28.03	CFU/mL1.4x	O Counted by:	arb 17.28.0

LEFT HAND			W.	ASH,1	RIGHT HAND			
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4	
MR	TUTE	108	21	ThT	THIC	98	. 11	
MTC	THIC	148	17	ThTC	THIC	93	8	
MZ				TUTC				
CFU/mL 1.3x105	Count	ed by : _ <i>Q</i>	1017.28.93	CFU/mL 9. 6×104	Counted by	ans	17.28.03	

LEFT HAND			W.	ASH 11	RIGHT HAND			
10 ⁻¹	10-2	10-2 10-3		10-1	10-2	10-3	10-4	
MT	MI	36	4	ThTL	153	11	1	
THIC	TRTC	26	3	DIT	160	23	3	
THR				九兀				
CFU/mL 3.1x 10 4	_ Counte	ed by : <i>App</i>	17.28.93	CFU/mLI-6 × 104	Counted by	: als	17.28.03.	

Calculations by: <u>JNB</u> /07·29·03 Raw data reviewed by <u>JNB</u> Calculations Verified by: <u>TL-/7-29·03</u> Raw data reviewed by <u>JNB</u> *10-1 dilution is the sum of 1.0 mL spread across 3 plates. Underlined values are used for calculation of CFU/mL 108.01.03

TNTC - Too Numerous To Count

Investigator's Signature:	2115	11 -	Date:	9	18	103	
	11 11 hour	V		mm	dd	уу	
		f					

	Cubicot	Initiala	_ L N	AP s	ubject #_		9		04	- 00	4000	
•	Subject	Initials _		<u> </u>	nplecr#_			•	Study N Page No		-12208 -125	35-106
}					A DAZIER	מר מרום	TIMBING		1 490 11	يد	- 22	
			<u>.</u>	•	ADVER	OE E	VENIS					
	Sy	mptom / E	vent	Onset Date	End Date	SAE ¹	Severity	Action Taken	Outcome F	Relation- ship		tigator ure/Date
	Pa	pula	>	7-25-03	3/7/03	N	1.	1	1	4	ACU.	in Julia
Ì	Entry Date	Comment/N	ote:	latter	1.0 8	, j	ant or	100 nists	m. &	P1. 8-	16-0	Initials
ł	7-29-	7		100	1	3 00		J.	M	14/N22	16.00	491
ţ	1-29-	77-1	Jorde 1	100	pup	us	son	wa		00		7.20
	8/11	11	rong	ong.	- gres	4 Cz	Kg.		,		-	1-290
	8/1/03	Han	eds & c	finger	- Ol	en	I M	O M	redica	Tion	رور	gh
		u	sed b									
				Onset Date	End Date	SAE	Severity	Action	Outcome	Relation-		stigator
	<u>s</u>	ymptom / E	event			Y/N	•	Taken		ship	Signa	ture/Date
•	Entry	Comment/I	Mata	<u>.</u>		<u> </u>				•	·	lmi4i-la
	Date	Comment	vote.			······································	**************************************			 -		Initials
										····	,	<u> </u>
) }											·	
										ı	•	
					T	SAE	η	Action		Relation-	Inve	estigator
•		Symptom /	Event	Onset Date	End Date	Y/N	Severity	Taken	Outcome	ship		ature/Date
					<u> </u>		'					,
	Entry Date	Comment	/Note:								-M	Initials
												·
					•						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	L									,		
	Note: Sever		y, Relatio 1=Mild	nship and	Outcome 2=Mod			letermine 3=Se		cipal inv	estiga [,]	tor.
	Relati	onship:	1=Definite)	2=Pro	bable		3=Po	ssible		4=Unre	lated
	Actio	n Taken:	1=None		2=Rx	Thera	ру	3=Di:	scontinued	Study	4=Othe	er (specify)
,	Outco	ome:	1=Resolve sequel			solved escribe	w/ seque e)	elae 3=Or	ngoing		4=Dea	th .

¹Serious Adverse Event/Experience

HTR Study No.: 03-122085-106

FOLLOW-UP VISIT

Page No.: IV - 256

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/29/03 mm dd yy	L,M,P	Permanent #:	03-122085-106

Date Subject Entered the Study: O7, 15, 03 mm dd yy	Follow-Up Visit Date: O7, 29, 03 mm dd yy			
Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection? YES NO If yes, complete below: Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.) Three red proposes on works hereof the first form				
Comments:				
Has the subject had any health related issues since the treatment procedure? If yes, complete below				
Comments:				
Medical Consultant's Signature:	Date 7 129 103 mm dd yy			

	DEM	OGRAPHICS/DER	MATOLOGICAL	MEDICAL HIS	TORY FO	RM	
	Visit Code	Date	Subject Initials	Subject Screen	1#:	Study#	
	Subject Qualification	07/15/03 mm dd yy	$\frac{P/A}{F}$ $\frac{D}{M}$	Permanent #:	7 03	3-122085-106	
		mm dd yy	L M L		4		
Gender:	☐ Male	Female .		Ag	se: <u>58</u>	Years	
Does the s	subject have any of	the following at the	treatment sites?				
	MATOLOGIC DIS				No,	Yes	Don't Know
1.	Psoriasis ?				1/		AKHOV
2.	Eczema?			-	- \ \ \ / /		
3.	Skin Cancer ?				V/		
4,	Skin Allergies? Pl	ease specify:			- //-		
5.	Hives ?				1/		
					V	11_	
Does the	Subject have any of	the following (pres	sent and past)?				
II. OTH	IER MEDICAL IN				No	Yes	Don't Know
1.	Allergies.? Please	specify.		.,,	<u></u>	·	
2.	Hepatitis?				<u> </u>		
3.	Heart and Vascular	r Disease? high b	olood pressur	e		V	
4.	Liver Disease?	J	ſ				
5.	Kidney Disease?				<u>/, </u>		
6.	Tuberculosis?				V		
7.	Diabetes? Contr	olled? Diet[] C	Oral [] Insulin []		V		
8.	Cancer?				V/		
9.	Auto-immune dise	ase (Lupus erythema	tosus, thyroiditis, A	IDS, etc.)?			
10.	Organ transplant?				\checkmark		
11.	Any other condition	on not listed? Pleas	e specify: high C	holesterol	_		
Is the su	bject taking any me			Thom (1	ע		
Г	DICATION				No	Yes	Don't Know
1.	Antibiotics, oral o	r systemic ?			1/		223011
2.		ls, ACTH, Anti-react	ion Drugs ?				
3.		? sem Libr		1xday		1	
4.	Insulin ?	· septim spile	eras econi	3 12 coup			
5.	Other? Welcho	1 625ma 1x	day - cho	Parton of W			
	1.0.0.10						
Comme	ents: Evust	a bong 11	xday - Hir mg 1xdau	1-blood	l pres	sure	
W (added as	per sur	ect 7/15/0	3 g&			
	n the above medical l	nistory, the subject is		0	Not qualit	fied for the st	udy.
Intervie	wer's Signature:	Bu	000000	Date:	07 1	15 103	3

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106.
Page No.: TV - 2558

#: Study #

		Visit Code Subject Qualification		Date	Subject Initials	Subject Screen #:	Study #	
				07,15,03 mm dd yy	PAD	Permanent #:	03-122085-106	
				IN	CLUSION CRITERL	A	<u> </u>	
Che	ck one					•		
YES /		NO	Subject:					
	1		1. Is 18	through 65 years?				
	X		2. Has	signed informed conser	nt?			
/_	1		3. Is he	ealthy as evidenced by a	responses on DCF 1?			<u>. </u>
	<u>X</u>		4. Ḥas	hands and wrists that a	re free of dermatoses,	cuts, lesions, and other sl	cin disorders ?	
<u> </u>						imately one (1) mm past		
V				illing to refrain from us wering, and handwashi		os (liquids and/or bars) fo ndy ?	r bathing,	
V	L		7. Is w	illing to refrain from u	sing anti-dandruff shar	npoo during the entire st	ady ?	
V		•	liqu		dorant/antiperspirant p		ns, creams, oils, dishwash study, unless prescribed	
V				villing to refrain from u sician for an intercurre		uring the entire study, un	less prescribed by a	
V				villing to refrain from u		ic antibiotic medication d ent illness ?	uring the entire study,	
			11. Is v	willing to comply with	all study protocol requ	irements?		
X				E	XCLUSION CRITER	·IA		
Cl YES	neck or	ne	A Subject	•				•
	V	X	1. Is o	currently participating i	in another clinical stud	y at this or any other faci	lity ?	
	V	1	2. Ha	s participated in any ty	pe of hand or arm was	h study within the past 7	days ?	
	V	1	3. Ha	s cuts, lesions, or other	skin disorders on thei	r hands or wrists?		
	V	1	4. Ha	s artificial nails or nail	tips?			
	V		5. Ha	s soap, detergent, antib	oiotic, Polysporin® and	l/or perfume allergies?		
	V	1	6. Ha	s eczema or psoriasis o	on their hands or wrists	?	/	
Pemale	Femal	e Ma	ale 7. Is	currently pregnant? 🗆		ld-bearing potential: Y	es D'No	
	V	1.	If.	of child bearing potenti	Surgically Sterile, year ial - β-HCG Test Resul	ts: negative post-men	opausal, year <u>1998</u> Sitive	
		1		currently lactating?				
,	V	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus						
	ν	erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?						
	V	1	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.					
	1,	1				the ingredients in antibac		
	•	. K. C	Qualified	tion and the information Not Qualified	for participation is		the subject is:	2
Reaso	ns for	disqual	ification:		interview	er's Initials/Date: UN	A AD	
Investig	ator's S	Signatu	re:	9 1 min	ll\	Date: 0/	$\frac{g}{dd}$ $\frac{\sqrt{3}}{yy}$	

HTR Study No.: 03-122085-106
Page No.: <u>W - 259</u>

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #			
Test Period	07/23/03 mm dd yy	P/A/D F M L	Permanent#: 7	03-122085-106			

				4
I. Is skin on subject's hands at If no, please indicate con				
II. Has subject used non-antib	_		· -	PYes DNo
III. Has subject been ill since the	he last visit? □Yes (Con	nplete below)	∃ No	
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) 🗷 No	
Based upon the above respon	ses, the subject is: 🗷 u	alified 🗆 Not	Qualified to cont	tinue on the study.
Reasons for disqualifica	tion:			
	•			
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT	ILLNESS
Date of Onset:	Date Reported:		Date Resol	ved:
Describe condition:			•	
	on taken (Complete belo	w) □Hospitalized	l 🛘 Other (exp	Consulted physician
	CON	COMITANT ME	DICATION	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		1 1	1 1	·
		1 1	1 1	
·		1 1	1 1	
Comments:				•
Interviewer's Signature:	om R. Hoveri	ı	Date: 07 /	23 / 03 dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL	of Sam	pling	Solution
--------	--------	-------	----------

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	$\frac{P}{F}$ $\frac{A}{M}$ $\frac{D}{L}$	Permanent #:	03-122085-106

		BAS	ELINE		
LEFT	HAND DILUTIO	NS	RIGHT	HAND DILUTI	ONS
10-4	10-5	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	165	22	TNTC	158	14
TNTC	150_	27_	TNTC	173	12
CFU/mL2.0×10	Counted by :	Ogn 17.25.03	CFU/mL .6×10	Counted by:	<u>On 1</u> 7.25.03

LEFT HAND			W	ASH 1	I	UGHT H	AND
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4
TNTC	242	- 67	6	TNTC	TUTC	40	8
TNTC	Q 254	- 78_	11	TNTC	TNTC	48	3
TNTC			•	TNTC			
CFU/mL 4.9 × 104	Counte	ed by : Q {	n 17/25.03	CFU/mL 4.4×104	Counted by:	gen 1	7.25.03
Dedident	t ustiv	nate c	hieto	countability	of plate		

LEFT HAND			W	ASH 11		RIGHT	HAND
10-1	10-2	10-3	10-4	10-1	10-2	10 ⁻³	10-4
TNTC	TNTC	51	6	TNTC	TNTC	50	5
TNTC	TNTC	61	5	TNTC	TNR	58	. 12
TNTC				TNTC			
CFU/mL 5.6×104	_ Counted	i by :	8n 17.25.03	CFU/mL 5.4 × 104	Counted by	<u> 982</u>	17.25.03

Calculations by: Tb /7.26.03 Raw data reviewed by Calculations Verified by: JNB /07.29.03 *10-1 dilution is the sum of 1.0 mL spread across 3 plates. Underlined values are used for calculation of CFU/mL TNTC – Too Numerous To Count	GRB 18.1.03
Investigator's Signature:	Date: / / mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 261

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Follow-up Visit	07/28/03 mm dd yy	$\frac{P/A/D}{FML}$	Permanent#: 7	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: O7 / 28 / 03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? THES TO NO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Comments.	
Has the subject had any health related issues since the treatmen TYES NO If yes, complete below	t procedure?
Comments:	
Medical Consultant's Signature:	Date 728,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: IV - 262

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: /23	Study#
Subject Qualification	07,15,03 mm dd yy	A/L/B F M L	Permanent #:	03-122085-106

	Quantitation	mm dd	уу	<u> </u>	<u>M</u>	<u>L</u>					
Gender:	☐ Male	√ Female	· .					A	.ge: <u> </u>	/_Years	
oes the su	bject have any of th	e following	at the ti	reatm	ent site	es?					
	IATOLOGIC DISC		······································						No	Yes	Don't
	Psoriasis ?										Know
	Eczema?										
	Skin Cáncer ?										
	Skin Allergies? Plea	se specify:					··································				
	Hives?	ase speeny.									<u> </u>
	ubject have any of t	ha following	(nrose)	nt and	nast)?						
	ER MEDICAL INF				· pasty.				No	Yes	Don't Know
1.	Allergies.? Please s	pecify.						····			
2.	Hepatitis?	L),									
3.	Heart and Vascular	Disease?					····			 	
4.	Liver Disease ?									<u> </u>	
	Kidney Disease ?										
6. Tuberculosis? 7. Diabetes? Controlled? Diet[] Oral[] Insulin[]											
8.	Cancer?	1100: 270:	<u> </u>	L J				· · · · · · · · · · · · · · · · · · ·			
9.	Auto-immune diseas	ce (Tumis en	themato	ens th	vroidit	ris AT	DS. e	etc.) ?			
10.	Organ transplant?	so (Eupus oi)	LACALACTIC	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							
11.	Any other condition	not listed ?	Please	snecif	v. A	101		•			
	ject taking any med						essi	·m	1,	<u> </u>	
	DICATION								No	Yes	Don't Know
1.	Antibiotics, oral or	systemic?	·						1		
2.	Cortisone, Steroids		i-reaction	n Dru	gs?				1/		
<u></u> 3.	Heart Medication ?				Ī		······································				
4.	Insulin ?								1		
5.	Other? Zdo	ft 50	ma	Ixd	au	(d	١٦٩٠	essim		V	
			- 0				9				
Commen	nts:										_
i											•
					······································						
Based on	the above medical hi	story, the sul	oject is:		₽Qu	alifie	d (or 🗆	Not qualif	fied for the	study.
Interviewer's Signature: Start (Randing Date: 67, 15, 03 mm dd yy											

Data Collection Form 2 SION / EXCLUSION FORM

YES

YES

Female

Reasons for disqualification:

Investigator's Signature:

HTR Study No.: 03-122085-106
Page No.: TV - 263

		INCLUSION / EXCLUSION FORM Page N							
		Visit	Code	Date	Subject Initials	Subject Screen #:	Study #		
		Subject 07/15/63 mm dd yy		A16,B	03-122085-106				
				INC	LUSION CRITERI	Ā	——————————————————————————————————————	-	
Che	ck one			,,,,,					
S	N)	Subject:						
_			1. Is 18	through 65 years?					
		ì	2. Has s	signed informed conser	nt?				
7			3. Is he	althy as evidenced by r	esponses on DCF 1?				
_			4. Has l	hands and wrists that a	re free of dermatoses,	cuts, lesions, and other	er skin disorders ?		
_			5. Has i	fingernails that extend	no longer than approx	kimately one (1) mm p	ast the nail bed?		
/				lling to refrain from us vering, and handwashir			s) for bathing,		
_			7. Is wi	lling to refrain from us	sing anti-dandruff sha	mpoo during the entire	e study ?		
/	,	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?							
/		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?							
/		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?							
/			11. Is w	illing to comply with a	ill study protocol requ	irements?			
			·	EX	CLUSION CRITER	RIA			
CI	neck one								
S	NO	N/A	Subject:						
T			1. Is c	urrently participating is	n another clinical stud	ly at this or any other	facility ?		
			2. Has	participated in any typ	oe of hand or arm was	h study within the pas	t 7 days ?	***************************************	
7	/		3. Has	cuts, lesions, or other	skin disorders on the	ir hands or wrists?			
			4. Has	artificial nails or nail	tips?				
\neg			5. Has	soap, detergent, antibi	iotic, Polysporin® an	d/or perfume allergies	?		
7				eczema or psoriasis o					
ile	Female	Male	7 Is gurrently pregnant 2 D.Ves. D.No. Of child-hearing notential: D.Ves. D.No.						
			8. Is currently lactating?						
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?						
		10. Has another medical condition which in the opinion of the Investigator would preclude participation?							
		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.							
	1	·	wo		agement or other bed	-ridden related care ro		·····	

Interviewer's Initials/Date:

Date:

 $\mathbf{m}\mathbf{m}$

dd

HTR Study No.: 03-122085-106
Page No.: W-264

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 123	Study#		
Test Period	07 / 23 / 03 mm dd yy	A/L/B F M L	Permanent#:	03-122085-106		

I. Is skin on subject's hands a If no, please indicate co	nd wrists still free of der	-	•	lisorders? EYes		
II. Has subject used non-antib	pacterial soap and follow			es DNo		
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	No			
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) 🖽 🗥 o			
Based upon the above respon	ses, the subject is: 🗗 🔾 u	alified Not	Qualified to contin	ue on the study.		
Reasons for disqualifica	ation:					
	•					
TO BE C	COMPLETED IF SUBJ	ECT HAS AN I	TERCURRENT I	LLNESS		
Date of Onset:	Date Reported	•	Date Resolve	ed:		
Describe condition:			·			
	-	7.11	- Holizon Carrier and Carrier			
Was reaction related to treatm	ent? [Not related] I	Possibly related	☐ Definitely related	Other (explain)		
Action Taken: None	Continued on study	Withdrawn from	the study Cor	nsulted physician		
☐ Medicat	ion taken (Complete belo	ow) []Hospitalized	l 🛘 Other (expla	in)		
Additional Comments:						
		COMITANT ME				
Medication	Total Daily Dose	Start Date	Stop Date	Indication		
(Oral or Systemic)	Total Daily Dose	mm / dd / yy	mm/dd/yy	(Reason for Taking)		
		1 1	1 1			
		1 1	1 1			
Comments:						
Interviewer's Signature:	<i>l</i> 0 -	, I	Date:07 /	23, 03		

mm

dd

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen # 123	Study#
07/23/03 mm dd yy	A/L/B F. M L	Permanent#:	03-122085-106

		В	ASELIN	Œ		
LEFT	T HAND DILUTI	ONS		RIGI	TT HAND DILUT	IONS
10-4	10-5	10 ⁻⁶		10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	143_	18		TNTC	136	18
TNTC	79_	19		TNTC	150_	13
CFU/mL1.7 YI	Ounted by:	NB 107.25.03		CFU/mL <u>L4×1</u>	O Counted by:	JNB 107-2503

LEFT HAND		WASH 1 RIGHT HAND					
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4
TNTC	TNTC	TNTC	32	TNTC	TNTC	81	15
TNTC	TNTC	TNTC	51	TNTC	TNTC	96	10
TNTC				TNTC			
CFU/mL 4.2×105	Count	ted by : JN	107.25.03	CFU/mL 8.8 × 10 4	Counted by	: JNB	107.25:03

LEFT HAND		WASH 11 RIGHT HAND					
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10-2	10 ⁻³	10⁴
TNTC	TNTZ	234	- 24	TNTC	TNR	152	- 29
TNTC	TYTZ	@ 278	49	TUTC	TNTC	197	- 26
TNTC				TNTC			
CFU/mL 3.1×105	Counte	ed by : <i>9</i>	Pn 17.25.03	CFU/mL 2.2 × 185	Counted by :	gen .	7,25.03

1 plates counted aux to courdability of plate 7.25.03 gh

Calculations by:	Qlb 18.1.03
Investigator's Signature:	Date: <u>9 18 103</u>

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 266

Visit Code	Da	te .	Subjec	et Initi	als	Subject Screen #:	Study #
Follow-up Visit	07/28 mm do	/03	AF	<u>, </u>	<u>'/ B</u>	Permanent #: 8	03-122085-106

Date Subject Entered the Study: 07/15/03	Follow-Up Visit Date: <u>07 / 28/03</u> mm dd yy
mm dd yy Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	
☐ YES NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatmen	t procedure?
☐ YES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Date
Co-Juin Jos M. O	7 128103 mm dd yy

HTR Study No.: 03-122085-106
Page No.: IV - 267

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 150	Study#
Subject Qualification	07/15/03 mm dd yy	$A_{FM}D_{L}$	Permanent#: 9	03-122085-106

	mm dd yy F M L			
Gender:	☐ Male ▼ Female .	ige: 46	Years	···
Does the s	ubject have any of the following at the treatment sites?			
I. DER	MATOLOGIC DISORDER	No	Yes	Don't Know
1.	Psoriasis ?	V ,	•	
2.	Eczema?	//		
3.	Skin Cancer ?	//		
4.	Skin Allergies? Please specify:			
5.	Hives ?	V		
Does the	Subject have any of the following (present and past)?			
п. отн	ER MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.	1//		
2.	Hepatitis?			
3.	Heart and Vascular Disease?			
4.	Liver Disease ?			
5.	Kidney Disease?			
6.	Tuberculosis?			
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8.	Cancer ?			
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	V	/	
10.	Organ transplant?			
11.	Any other condition not listed? Please specify:	·		
Is the su	bject taking any medication? If yes, please specify below:			
III. ME	DICATION	No /	Yes	Don't Know
1.	Antibiotics, oral or systemic?	V,		
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3.	Heart Medication ?			
4.	Insulin ?			
5.	Other ?	\ \V		
Comme	nts:			
Based or	the above medical history, the subject is: Qualified or [Not qualifie	ed for the	study.
Interviev	ver's Signature: Date:	07/1	5 / 0	3 yy
L	for the position of			J J

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: W - 268

Subject Screen #: Subject Initials Date Visit Code Study # Subject Permanent #: 03-122085-106 Qualification INCLUSION CRITERIA Check one YES NO Subject: 1. Is 18 through 65 years? 2. Has signed informed consent? 3. Is healthy as evidenced by responses on DCF 1? 4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders? 5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed? 6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study? 7. Is willing to refrain from using anti-dandruff shampoo during the entire study? V 8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness? 9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness? 10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness? 11. Is willing to comply with all study protocol requirements? **EXCLUSION CRITERIA** Check one ... YES NO N/A Subject: 1. Is currently participating in another clinical study at this or any other facility? 2. Has participated in any type of hand or arm wash study within the past 7 days? 3. Has cuts, lesions, or other skin disorders on their hands or wrists? 4. Has artificial nails or nail tips? 5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies? 6. Has eczema or psoriasis on their hands or wrists? 7. Is currently pregnant? ☐ Yes No Of child-bearing potential: W Yes D No Female Male Female ☐ Surgically Sterile, year ☐ Post-menopausal, year If of child bearing potential - β-HCG Test Results: 2 negative positive 8. Is currently lactating? 9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation? 11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles. 12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps? Based upon dermat6logic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: Qualified for participation in this study. ☐ Not Qualified Interviewer's Initials/Date: Reasons for disqualification:

Date:

dd

Investigator's Signature:

HTR Study No.: 03-122085-106
Page No.: W-269

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/24/03 mm dd yy	A / P / D F M L	Permanent#:	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? EYes \(\text{INO} \) If no, please indicate condition:							
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes \text{INo} \text{If no, please explain:}							
III. Has subject been ill since the	e last visit? Yes (Cor	nplete below)	No No				
IV. Has subject used any new or	al or topical medication	n? □Yes (Comple	te below) 🖽 No				
Based upon the above response	es, the subject is: 🗷 u	alified 🗆 Not (Qualified to cont	inue on the study.			
Reasons for disqualificati	on:			·			
	•						
TO BE CO	MPLETED IF SUBJ	ECT HAS AN IN	ITERCURRENT	ILLNESS			
Date of Onset:	Date Reported	•	Date Resol	ved:			
Describe condition:			•	•			
	ntinued on study n taken (Complete belo	Withdrawn from	the study 🔲 C	Consulted physician			
	CON	COMITANT ME	DICATION				
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)			
		1 1	1 1				
		1 1	1 1				
Comments:							
			A7	2//			

Tutamaiana) - Ciamatana	/ ^	, ,	Date: 07 / 24 / 03
- Interviewer's Signature:	Josep K	Horns	mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

		x	
Test Date	Subject Initials	Subject Screen #	Study#
07 /24 /03 mm dd yy	A_1P_1D F. M. L.	Permanent #:	03-122085-106

		BA	SELINE			
LE	FT HAND DILU	TIONS	RIGH	RIGHT HAND DILUTIONS		
10-4	10 ⁻⁵	10-6	10-4	10-5	10 ⁻⁶	
THIC	226	9	TWIC	224	20	
TATE	190	18	TUTC	138	12	
CFU/mL2.1x	Counted by:	645 / 7-28-03	CFU/mL 18X10	Counted by:	<u>545 /</u> 7-28-03	

LEFT HAND		•	WASH 1			RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10-2	10 ⁻³	10-4		
THIC	THIC	181	26	TNIC	Three	224	25		
TUTC	TNTC	178	21	TNTC	TNTC	£13	22		
DITC				TNTC			•		
CFU/mL 2.1 x 105	Coun	ted by : 45	17-28-03	CFU/mL 2.3 x 10 5	_ Counted by	7: 545	17-28-03.		

LEFT HAND		WASH 11				RIGHT	HAND
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4
TWTC	TWTU	38	5	TWT	TWTC	31	\
twi	TWTU	45	4	THIC	TUTO	34	ン
TUTO				TWTU			
CFU/mL4.2 × 104	Counte	d by : <u>Pr S</u>	\1'98'a2	CFU/mL 3.2x104	Counted by	: <u>RS</u>	17.28.03

Calculations by:	JNB	107.29.03	Raw data reviewed by _	als	18.1.93	
Calculations Veri	fied by:	Ta 17	29.03			
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.						
Underlined values are used for calculation of CFU/mL						

TNTC - Too Numerous To Count

Investigator's Signature:	Date: 8 18 103
19 hull	mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: 11 - 27/

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07, 29, 03	A P D	Permanent#: 9	03-122085-106

Date Subject Entered the Study: 07/15/03	Follow-Up Visit Date: 07,29,03
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
☐ YES NO If yes, complete below:	·
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	•
) }	
Has the subject had any health related issues since the treatmen	t procedure?
TYES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Date 7 129 10 3 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>IV - 272</u>

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07/15/03 mm dd yy	R/L/M F M L	Permanent #:	03-122085-106

No /	Yes	Know
+	8	†
	1	1
No	Yes	Don't Know
U		
No	Yes	Don't Know
~		
1		

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: 112-273

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	07/5/63 mm dd yy	RIL, M f m 1	Permanent #:	03-122085-106
	73.74	TY YICKONI CONTINUES	A	

			INCLUSION CRITERIA
	eck one	_	
YES	No.	0	Subject:
			1. Is 18 through 65 years?
			2. Has signed informed consent?
			3. Is healthy as evidenced by responses on DCF 1?
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?
/			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?
	-		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?
			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?
/	`		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?
	1		11. Is willing to comply with all study protocol requirements?
			EXCLUSION CRITERIA
C	heck one		
YES	NO	N/A	Subject:
i			1. Is currently participating in another clinical study at this or any other facility?
			2. Has participated in any type of hand or arm wash study within the past 7 days?
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?
			4. Has artificial nails or nail tips?
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?
			6. Has eczema or psoriasis on their hands or wrists?
Female	Female	Male	7. Is currently pregnant? Yes No Of child-bearing potential: Yes No Surgically Sterile, year Post-menopausal, year If of child bearing potential - β-HCG Test Results: negative positive 8. Is currently lactating?
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?
			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of
	1	-	wounds, intravenous management or other bed-ridden related care roles. 12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?
	d upon der	₽ Qua	7115/2
	gator's Sig		9 mm dd yy

HTR Study No.: 03-122085-106
Page No.: W - 274

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

74.7	TERCORRENT IL	DIABON COMEON	GIVILL MEDICATIO	TI LOKUL
Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/23/03 mm dd yy	<u>R / L / M</u> F M L	Permanent #:	03-122085-106

II. Has subject used non-antil	-	ed the instructions		es □No
II no, piease explain:	the lest visit? [Was (Con		,	
•				
IV. Has subject used any new			•	
Based upon the above respon				•
Reasons for disqualine	ation:			
TO BE O	COMPLETED IF SUBJ	ECT HAS AN I	TERCURRENT II	LLNESS
Date of Onset:	Date Reported	•	Date Resolve	ed:
Describe condition:				
Was reaction related to treatm Action Taken: □None □ (nent? Not related Continued on study Complete belo	Possibly related Withdrawn from ow) □Hospitalized	Definitely related the study	Other (explain) nsulted physician in)
Was reaction related to treatm Action Taken: None Medicate Additional Comments:	nent? Not related Continued on study Complete belo	Possibly related Withdrawn from ow) []Hospitalized	Definitely related the study Con Other (expla	Other (explain) nsulted physician in)
Was reaction related to treatm Action Taken: □None □ (□ Medicat	nent? Not related Continued on study Complete belo	Possibly related Withdrawn from ow) □Hospitalized	Definitely related the study	Other (explain) nsulted physician in)
Was reaction related to treatm Action Taken: None O Medicate Additional Comments:	nent? Not related Continued on study Complete belo	Possibly related Withdrawn from ow) []Hospitalized COMITANT ME	Definitely related the study Con Other (expla	Other (explain) nsulted physician in) Indication
Was reaction related to treatm Action Taken: None Medicate Additional Comments: Medication	nent? Not related Continued on study Complete belo	Possibly related Withdrawn from Ow) []Hospitalized COMITANT ME Start Date mm / dd / yy	Definitely related the study Con Other (expla	Other (explain) nsulted physician in) Indication
Was reaction related to treatm Action Taken: None Medicate Additional Comments: Medication	nent? Not related Continued on study Complete belo	Possibly related Withdrawn from DW Hospitalized COMITANT ME Start Date mm / dd / yy / /	Definitely related the study Con Other (explanation) CDICATION Stop Date mm / dd / yy	Other (explain) nsulted physician in) Indication

Interrieswar's Signature: 0 Ht SA	Date: 07/23/03
Interviewer's Signature: Betty M. Conover	mm dd yy

${\bf HEALTH\ CARE\ PERSONNEL\ HANDWASH\ BACTERIAL\ COUNTS}$

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	R/L/M F. M L	Permanent #:	03-122085-106

]	BASELIN	(E		
LEF	T HAND DILUTI	ONS		RIGI	HT HAND DILUT	IONS
10-4	10-5	10 ⁻⁶		10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	156_	17		TNTC	146	20
TNTC	T42	10		TNTC	T38_	24
CFU/mL\.5x	Counted by:	INB 107.25:03		CFU/mL /.4X	O Counted by:	NB 107.25:03

LEFT HAND			W.	VASH 1		RIGHT HAND		
10 ⁻¹	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10-3	10-4	
TNTC	TNTC	TNTC	88-	TNTC	TNTC	TNTC	5L	
TNTC	THIC	TNTC	92	TNTC	TNTC	TNTC	53/	
TNTC				TNTC				
CFU/mL 9.2 × 10.5	Count	ed by : JNB	107.25.03	CFU/mL <u>5.2×10⁻⁵</u>	Counted by	: JNB	107.25.03.	

LEFT HAND		WASH 11					HAND
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4
TNTC	TNTC	155	19	TNTC	TNTC	172	29_
TNTC	TNTC	201	24	TNTC	TNTC	197	30
TNTC				TNTC			
CFU/mL 1. 8 × 10 5	Count	ted by : JNB	107.25.03	CFU/mL 2 4x 10 5	Counted by	y: JNB	/ 67·25·13 <u>.</u>

Calculations by: Raw data reviewed by _	als	18.1.03
Calculations Verified by: JNB /07-29-03		
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.		
Underlined values are used for calculation of CFU/mL		
TNTC – Too Numerous To Count		

Investigator's Signature:	Date: 8 111 103
11 Mm/V	mm dd yy

Data Collection Form 6 FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IX - 276

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07, 28,03 mm dd yy	R/L/M F M L	Permanent#:	03-122085-106

Date Subject Entered the Study: O7/15/03 mm dd yy	Follow-Up Visit Date: O7, 28, 03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
☐ YES ☑ NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/s	severity/locations, etc.)
Comments:	
	,
Has the subject had any health related issues since the treatmen	at procedure?
TYES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Date 7,28,03 mm dd yy

HTR Study No.: 03-122085-106
Page No. <u>IV</u> - 277

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

r		JGRAPHICS/DER		Subject Screen			
	Visit Code	Date	Subject Initials	108		Study#	
	Subject Qualification	07/15/03 mm dd yy	SILIB FM L	Permanent#	<u> </u>	03-122085-106	
					.ge: 63	3 Years	
ender:	☐ Male	Female .		P	ي ge:	rears	
oes the sul	bject have any of t	the following at the	treatment sites?				
I. DERM.	ATOLOGIC DIS	ORDER			No	Yes	Don't Know
1. P	soriasis ?	·			//	1	ALMOIT
	Eczema ?				//		
	Skin Cancer ?				V		
4. S	Skin Allergies? Ple	ease specify:			1		
	Tives ?				V		
Does the Su	thiect have any of	the following (pres	ent and past)?		<u> </u>	······································	
	R MEDICAL IN				No	Yes	Don't
					110	105/	Know
		specify. Season	<u> 91 </u>		 	- V	
	Hepatitis ?			· · · · · · · · · · · · · · · · · · ·	V		
	Heart and Vascular	Disease? high b	plood pressure	·	<u> </u>	- V	
	Liver Disease?				V/		<u> </u>
	Kidney Disease?				\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		
	Tuberculosis?				V		<u> </u>
	Diabetes? Contr	olled? Diet[] C	oral[] Insulin[]		- V/		
	Cancer?				V/		ļ
		ase (Lupus erythema	tosus, thyroiditis, A	IDS, etc.) ?	V		<u> </u>
	Organ transplant?				IV_		
11.	Any other condition	n not listed? Pleas	e specify: hypothy	roldism	1		<u> </u>
Is the subj	ect taking any me	dication? If yes, pl	ease specify below:	· }			
III. MED	ICATION	and the second seco		المان با غير و يون ^{ي م} ان المان بي و مان المان بي و يون ^{ي مان} المان بي و يون ^{ي مان} المان بي ويون ^{ي و} المان	No	Yes	Don't Knov
1.	Antibiotics, oral or	r systemic ?			V		
2.	•	s, ACTH, Anti-react	ion Drugs ?		V	,	
3.	Heart Medication	? Avapro :	250mg Ixda	1			
4.	Insulin?		J				
5.	Other?	ee below					
Comment	ź <u> </u>	eds: Synthroi	d 0.112 12	day hyp	othyroidis	m	
Based on t	he above medical h	istory, the subject is	: Z Qualifie	ed or 🗆	Not qua	lified for the	study.
	r's Signature:	· D	asemeyer	Date:	07 /	15 103	<u>у</u> у

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: 12-278

		Vis	sit Code	Date	Subject Initials	Subject Scr	een #:	Study#	
			ubject lification	07,15,03 mm dd yy	S/L/B	Permanent	#: 1\	03-122085-106	
				INC	CLUSION CRITERL	A.			
	ck on					•			
YES	<u>. 1 </u>	МО	Subject:			······			
<u>v /</u>				through 65 years?		·			
V_{-}	4			signed informed conser					
-V/	4.			althy as evidenced by			1 .1		
//	4			hands and wrists that a					
-V	/			fingernails that extend					
<u>//</u>	4		shov	illing to refrain from us vering, and handwashin	ng during the entire st	idy?			
V,	4	·		illing to refrain from us				``	
V			liqui		dorant/antiperspirant p			ns, creams, oils, dishwashi study, unless prescribed b	
V				illing to refrain from u sician for an intercurre		iring the entir	e study, un	less prescribed by a	
V				rilling to refrain from u ess prescribed by a phy			edication d	luring the entire study,	
V			11. Is w	villing to comply with a	all study protocol requ	irements?			
				EX	KCLUSION CRITER	IA			
C	heck o	ne							
YES	NO	/ N/A							
	V	4.		urrently participating i		.,			
	$\underline{\hspace{1em} \nu}$	/ _		s participated in any ty				days?	
	$-\nu$	Z		s cuts, lesions, or other		r hands or wri	sts ?		
	V	4_		s artificial nails or nail					
	V	4		s soap, detergent, antib			llergies?		
	レ	4_		s eczema or psoriasis o			Zakia I. CL. XI		
emale	Fema	lea Ma	ne l	currently pregnant? ☐ ☐ of child bearing potenti	Surgically Sterile, year	· 52	Post-men	lopausal, year 99	
	V		8. Is	currently lactating?					
,	L	1	he	s been medically diagr patitis, an organ transp thematosus, thyroiditi	lant, an immunologic o	lisease such as			
	L	1		as another medical con eclude participation?	dition which in the opi	nion of the In	vestigator v	would	
	1	1		as any responsibility fo ounds, intravenous ma				ilities for diapering, care o	f
	V		12. Ha	s a known sensitivity t	o isopropyl alcohol or	the ingredient	s in antibac	cterial soaps ?	
	-	· B/C	Qualified	ion and the informatio Not Qualified	for participation i	n this study.			
Reaso	ns for	disqual	ification:		Interview	er's Initials/D		B 107:15:03	-
Investic	rator's	Signatu	re:	00	a	Date: _	081	10 1 03	ļ

HTR Study No.: 03-122085-106 Page No.: <u>W - 279</u>

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

A4.1	Traccordent	DIAMODI COLICOLI		X . X
Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/23/03 mm dd yy	S/L/B F M L	Permanent #:	03-122085-106

	[
		1 1	/ /	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
	Continued on study tion taken (Complete belo	Withdrawn from ow) □Hospitalized	the study Cor	nsulted physician
Date of Onset: Describe condition:			•	d:
TO BE C	COMPLETED IF SUBJ	ECT HAS AN IN	TERCURRENT II	LLNESS
Reasons for disqualifica	ation:			
Based upon the above respon		•	•	ue on the study.
II. Has subject been ill since tV. Has subject used any new		aproof color,		
				es
	ndition:			•

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	S, L, B F M L	Permanent #:	03-122085-106

		I	BASELI	VE.		
LE	FT HAND DILUT	TONS		RIGH	IT HAND DILU	TIONS
10-4	10*5	10 ⁻⁶		10-4	10 ⁻⁵	10-6
TNTC	145_	20		TNTC	180_	26_
TNTC	T55	12		TNTC	194	21_
CFU/mL \5)	Counted by:	JNB 107.26.03		CFU/mL2. XI	Ounted by:	INB 107.25.03

LEFT HAND			W.	ASH 1	RIGHT HAND		
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10-4
TNTC	TNTC	152_	- 17	TNTC	TNTC	150	28_
TNTC	TNTC	T79_	21	TNTC	TNIC	277	0 24_
TNTC				TNTC			
CFU/mL 1.6 X 10-5	_ Counte	ed by: JNE	3 107.25.63	CFU/mL2-4 y 10 5	Counted by	:JNB	M·25·03.

LEFT HAND			RIGHT HAND				
10-1	10-2	10-3	10-4	10 ⁻¹	10-2	10-3	10 ⁻⁴
TNTC	TNTC	124	+ 18	TNTC	TNTZ	137	. 14
TNTC	TNTC	154	- 15	TNR	TNTC	T27	15
TNTC				TNTC			
CFU/mL 1.4×105	_ Counted	l by :	On 17.25.03	CFU/mL 1.3 x 10 5	_ Counted by	: <u>9</u> 8n /	7.25.03

Calculations by: 16 / 7-26.03 Raw data reviewed by	UKD 181.03
Calculations Verified by:	
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.	
Underlined values are used for calculation of CFU/mL	
TNTC - Too Numerous To Count	
@ Did not estimate due to countability of the plant	ate. JNB 07:25:03
Investigator's Signature:	Date: 8 / 11 / 03 mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106
Page No.: 11-28

Visit Code	D	ate	Subjec	t Initials		Subject Screen #:	Study#
Follow-up Visit	07/2	8/03 dd yy	S	<u>/ L /</u>	B	Permanent #: //	03-122085-106

Date Subject Entered the Study:	Follow-Up Visit Date:							
07,15,03	07,28,03							
mm dd yy	mm dd yy							
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?							
☐ YES NO If yes, complete below:								
Clinical Observations: (Include date of onset and descriptions/s	severity/locations, etc.)							
Comments:								
Has the subject had any health related issues since the treatmen	at procedure?							
☐ YES NO If yes, complete below								
Comments:								
Medical Consultant's Signature:	Date 7 128103 mm dd yy							

HTR Study No.: 03-122085-106
Page No.: 1V - 282

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,									
Visit Code	Date	Subject Initials	Subject Screen #:	Study#					
Subject Qualification	07/5/03 mm dd yy	E/L/G F M L	Permanent #:	03-122085-106					

oes the subject have any of the following at the treatment sites?	- T		Don't
I. DERMATOLOGIC DISORDER	No	Yes	Know
1. Psoriasis?			
2. Eczema?			
3. Skin Cancer?			
4. Skin Allergies? Please specify:	·~		
5. Hives?			
Does the Subject have any of the following (present and past)?			
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	<i>\\</i>	<u> </u>	<u> </u>
2. Hepatitis?			
3. Heart and Vascular Disease?			
4. Liver Disease ?			
5. Kidney Disease ?			
6. Tuberculosis?			
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8. Cancer?	<u></u>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?			
10. Organ transplant?			
11. Any other condition not listed? Please specify: a sthrma.			
Is the subject taking any medication? If yes, please specify below: dizzine	sS		
III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3. Heart Medication ?			
4. Insulin?			
5. Other? Singulain 10mg (asthma)		1	
comments; 263 Phenagrin Smg Ikday (dizzinus) Tylenol Soma Ikday (headachus) Ortho-Tryct Fry Tricyclen (birth con	trol)		
Based on the above medical history, the subject is: Qualified or	Not quali	fied for the	study.

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>TV - 28</u>3

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	07/15/03	EILIG	Permanent#: 12	03-122085-106

			INCLUSION CRITERIA					
Ch	eck one		·					
YES	N	<u>o</u>	Subject:					
			1. Is 18 through 65 years?					
			2. Has signed informed consent?					
3. Is healthy as evidenced by responses on DCF 1?								
4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?								
	_		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?					
/			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?					
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?					
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?					
_			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?					
/	- `		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?					
			11. Is willing to comply with all study protocol requirements?					
			EXCLUSION CRITERIA					
	Check one	20.0	`					
YES	NO	N/A	Subject:					
			1. Is currently participating in another clinical study at this or any other facility?					
	/		2. Has participated in any type of hand or arm wash study within the past 7 days?					
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?					
	./		4. Has artificial nails or nail tips?					
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
			6. Has eczema or psoriasis on their hands or wrists?					
Female	Female	Male	7. Is currently pregnant? □ Yes □ No Of child-bearing potential □ Yes □ No □ Surgically Sterile, year □ Post-menopausal, year If of child bearing potential - β-HCG Test Results: If negative □ positive 7/24/03 ggs. 8. Is currently lactating?					
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?					
	/		10. Has another medical condition which in the opinion of the Investigator would preclude participation?					
	/		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.					
			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?					
		∠ Qui						
	gator's Sig		Date: 08/10/03 mm dd yy					

HTR Study No.: 03-122085-106
Page No.: W - 284

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

,11,	INTERCORRENT ILEMESS / CONCOMITANT MEDICATION FORM									
Visit Code	Date	Subject Initials	Subject Screen #:	Study#						
Test Period	67/24/03 mm dd yy	E/L/G F M L	Permanent #:	03-122085-106						

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Exes \(\subsetential \text{No} \) If no, please indicate condition:										
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? EYes [No If no, please explain:										
III. Has subject been ill since the	III. Has subject been ill since the last visit? Yes (Complete below) No									
IV. Has subject used any new or	ral or topical medication	n? □Yes (Comple	te below) 🖽 o							
Based upon the above response	es, the subject is: 🗷 Qu	ialified 🗆 Not	Qualified to contir	nue on the study.						
Reasons for disqualificati	ion:									
TO BE CO	MPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS						
Date of Onset:	Date Reported	•	Date Resolve	×d:						
Describe condition:										
Was reaction related to treatmer			•	•						
Action Taken: None Co	ntinued on study \Box	Withdrawn from	the study \(\Box	nsulted physician						
☐ Medicatio	n taken (Complete belo	ow) [Hospitalized	l Other (expla	in)						
Additional Comments:										
	CON	COMITANT ME	DICATION							
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)						
		1 1	1 1							
		1 1	1 1							
Comments:										
Interviewer's Signature:	Interviewer's Signature: / Date: 07/04/03									

					A ==	544	-	
Interviewer's Signature:	,	^		Date:	011	NY /	20	
mici viewei s bignature.	2non	<i>K</i> .	Horron		mm	dd	VV	
<u> </u>	<u> </u>	,	110					

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07 /24 /03 mm dd yy	E/L/G F. M L	Permanent #:	03-122085-106

BASELINE								
LEF	T HAND DILUI	TIONS	RIGH	IT HAND DILUT	TIONS			
10-4	10 ⁻⁵	10-6		10-4	10°5	10-6		
TNTC	141	13		TNTC	134	13		
TNTC	132	16		TNTC	135	13		
CFU/mLJ.4x1	δ ⁷ Counted by:	JNB 107.28:03	CFU/mL1-3XIC	Counted by:	INB 107.28.03			

LEFT HAND			W	ASH 1		RIGHT	HAND
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	10-4
TNTC	TNTC	66	10	TNTC	TNTC	111	11
TNTC	TNTC	90	11	TNTC	TNTC	106	11
TNTC				TNTC			
CFU/mL 7.8×104	_ Count	ed by : JNR	3 /07·28·03	CFU/mL 1.1x105	Counted by :	JNB	107.28.03

LEFT HAND		W	ASH 11	RIGHT HAND			
10 ⁻¹	10-2	10-3	10-4	10 ⁻¹	10-2	10-3	10-4
TNTC	75	17	ļ	TNTC	80	10	3
TNTC	798	14	0	TNTC	960	16	1
TNTC				TNTC		1	
CFU/mL 8.6×10 ³	Count	ed by : JNB	107.28.03	CFU/mL8.8X10 ³	Counted by	y:JNB	107.28.03

Calculations by: JNB 107.29.03 Raw data reviewed by	als	18.1.03
Calculations Verified by: The 17-29.63		
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.		
Underlined values are used for calculation of CFU/mL		
TNTC - Too Numerous To Count		

Investigator's Signature:	5 11-	Date:	8	111	103	
	mil 1		mm	dd	уу	
	X					

			Data Con	ection form	A.			
	Subject Initials	ELG s	Subject #	12	8	Study No.	03-12208	35-106
				·	F	age No.	II-29	36
۱)		•	ADVERSE	EVENTS				
	Symptom / Event	Onset Date	YIN		Action Ou Taken	itcome Relat		tigator ure/Date
	red bumps	7/25/03	8/11/03 N	`		14	C. Lein	JORIAN
	Entry Comment/Note:	hobally a	due to I	at or	ganis	m ex	9-6-13	Initials
	7/28/03 red	bumps	on rio	let com	d let	t Show	id.	OS4
	3/11/03 Hand	clean 1	used con	Temano 1	0 10 M		,	0
	2 times			(1	103			
			1					
				1				<u> </u>
	Symptom / Event	Onset Date	End Date SAE	Severity	Action Taken			stigator ture/Date
	see above	for date	3/1/10	23				
	Entry Comment/Note:							Initials
	7-29-03 Three	- red by	apula o	n ba	oho az	hora	6	67.0
`\		77	P					
)	/	· · · · · · · · · · · · · · · · · · ·				****		
				94				
					•			_1
	Symptom / Even	t Onset Dat	te End Date SA		Action Taken			estigator ature/Date
				·				
	Entry Comment/Note:	·						Initials
	54.0							<u> </u>
	·							
							•.	
			•					
	Note: Severity, Ro		Outcome M 2=Moderat		termined 3=Seve		al investiga	tor.
	, i	Definite	2=Probabl	e	3=Poss	ible	4=Unre	elated
	Action Taken: 1=1	None	2=Rx Ther	ару	3=Disc	ontinued Stud	dy 4=Othe	er (specify
ş	Outcome.	Resolved w/o sequelae	2=Resolve (descri	ed w/ sequela be)	e 3=Ongo	oing	4=Dea	th

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: 11 - 287

Visit Code	נ	Date		Subject	t Initia	als	Subject Screen #:	Study#
Follow-up Visit	07/2 mm	2910 dd	<u>ろ</u> yy	E	<u>/</u> <u>M</u>	<u>/</u> G	Permanent#: 12	03-122085-106

Date Subject Entered the Study: 07,15,03 mm dd yy	Follow-Up Visit Date: O7,29,03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? YES NO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s 3 red pufula on base Onset 7-25-03	everity/locations, etc.) of dard
Comments:	
Has the subject had any health related issues since the treatmen	t procedure?
Comments:	
Medical Consultant's Signature:	Date 7,29,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: 12-288

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07/15/03 mm dd yy	R/E/P FML	Permanent#: 13	03-122085-106

I. DER	MATOLOGIC DISORDER	No	Yes	Don't						
1.	Psoriasis ?			Know						
2.	Eczema?									
3.	Skin Cancer ?									
3. 4.	Skin Allergies? Please specify:									
5.	Hives?									
	Subject have any of the following (present and past)?									
п. отн	ER MEDICAL INFORMATION	No	Yes	Don't Know						
1.	Allergies.? Please specify.	<u> </u>								
2.	Hepatitis ?	· ·								
3.	Heart and Vascular Disease?	<u></u>								
4.	Liver Disease ?									
5.	Kidney Disease ?									
6.	Tuberculosis?									
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]			<u> </u>						
8.	Cancer ?	<u> </u>								
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	<u> </u>								
10.	Organ transplant ?	\(\sigma \)								
11.	Any other condition not listed? Please specify:	<u> </u>		1						
Is the su	Is the subject taking any medication? If yes, please specify below:									
III. ME	DICATION	No	Yes	Don't Know						
1.	Antibiotics, oral or systemic?	V								
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	<u></u>								
3.	Heart Medication ?	<u> </u>								
4.	Insulin ?	-								
5.	Other?		<u> </u>							
Comme	nts:									

mm

dd

уу

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085,106 Page No.: <u>TV - 281</u>

				•
Visit Code	Date	Subject Ínitials	Subject Screen #:	Study #
Subject Qualification	07, 15, 03 mm dd yy	RIER	Permanent#:	03-122085-106

			INCLUSION CRITERIA						
C	heck one								
YES	N	NO Subject:							
			1. Is 18 through 65 years?						
	2. Has signed informed consent?								
3. Is healthy as evidenced by responses on DCF 1?									
4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?									
	-		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?						
_			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?						
سب	-		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?						
✓	•		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?						
	-		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?						
			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?						
_			11. Is willing to comply with all study protocol requirements?						
			EXCLUSION CRITERIA						
) YES	Check one NO	N/A	Subject:						
			1. Is currently participating in another clinical study at this or any other facility?						
			2. Has participated in any type of hand or arm wash study within the past 7 days?						
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?						
			4. Has artificial nails or nail tips?						
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?						
			6. Has eczema or psoriasis on their hands or wrists?						
Female	Female	Male	 7. Is currently pregnant? □ Yes □ No Of child-bearing potential: □ Yes □ No □ Surgically Sterile, year □ Post-menopausal, year □ If of child bearing potential - β-HCG Test Results: □ negative □ positive 8. Is currently lactating? 						
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?						
			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.						
	17	1	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?						
	d upon der	□ Qua							
)	Investigator's Signature: Date: 08/10/03 mm dd yy								

HTR Study No.: 03-122085-106
Page No.: W - 290

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07,24,03 mm dd yy	R/E/P F M L	Permanent #:	03-122085-106

I. Is skin on subject's hands at If no, please indicate con			•				
II. Has subject used non-antib			= -	es 🗆 No			
III. Has subject been ill since the	he last visit? □Yes (Cor	nplete below)	No				
IV. Has subject used any new of	oral or topical medication	n? □Yes (Comple	te below) 🖾 🗸 o				
Based upon the above respon	ses, the subject is: 🗗 🕡	alified Not	Qualified to contin	ue on the study.			
Reasons for disqualifica	ation:						
TO BE C	OMPLETED IF SUBJ	ECT HAS AN II	TERCURRENT D	LLNESS			
Date of Onset:	Date Reported	•	Date Resolve	od:			
Describe condition:			•				
Was reaction related to treatme	ent? 🗆 Not related 🗀 1	Possibly related	☐ Definitely related	Other (explain)			
Action Taken: None	Continued on study	Withdrawn from	the study \(\Box\) Co:	nsulted physician			
	ion taken (Complete belo		-	- '			
Additional Comments:	· -			•			
Medication		COMITANT MI Start Date	Stop Date	Indication			
(Oral or Systemic)	Total Daily Dose	mm / dd / yy	mm / dd / yy	(Reason for Taking)			
		1 1	/ /				
		1 1	1 1				
Comments:		and the second of the second o					
· Interviewer's Signature:	11 -	, 1	Date: 07/6	24 / 03			

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date Subject Initials		Subject Screen #	Study#	
07 /24 /03 mm dd yy	R/E/P F M L	Permanent #:	03-122085-106	

			BASELI	NE		
LEFT	HAND DILU	rions		RIGI	TT HAND DILU	TIONS
10-4	10 ⁻⁵	10 ⁻⁶		10-4	10-5	10-6
TNTC	191	24		TNTC	142	11
TNTC	119	23		TNTC	122	16
CFU/mL/-6X/	Counted by:	JNB 107.28.02	}	CFU/mL/.3x/	O 7 Counted by	JNB 107:28:03

LEFT HAND			WASH 1			RIGHT HAND		
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10-3	10-4	
TNTC	TNTC	127	24	TNTC	TNTC	199	16	
TNTC	TNTC	229	18	TNTC	TNTC	148	19	
TNTC				TNTC			•	
CFU/mL/.8x/05	Count	ed by JNB	107-2803	CFU/mL/1.7x/0 ⁵	Counted by	: JNB	107.28.03	

LEFT HAND		WASH 11				RIGHT HAND		
10-1	10 ⁻²	10 ⁻³	10-4	10-1	10-2	10-3	10-4	
TNTC	100	16	2	TNTC	109.	21	2	
TNTC	107	14	0	TNTC	T26	16	0	
TNTC				TNTC				
CFU/mL 1.0x10+	Counte	ed by: JNE	07.28.03	CFU/mL1. 2x104	Counted by	/:JNB	107.28.03	

Calculations by: _	JNB	107.29.03 Raw data reviewed by	ales	18.1.03		
Calculations Verif	fied by:	TU 17:29.03				
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.						
Underlined values are used for calculation of CFU/mL						

TNTC - Too Numerous To Count

Investigator's Signature:	Date: 18/1/103
10 Mall	mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 292

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07, 29, 03 mm dd yy	RIEIP F M L	Permanent #: 13	03-122085-106

Date Subject Entered the Study: 07/15/03	08/01/03 - 07: 29:03
mm dd yy	mm dd yy 8/1/03
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
TYES NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
、) (.	
Has the subject had any health related issues since the treatment	t procedure?
☐ YES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Pate S 1 03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>TV - 293</u>

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	<u>57,21,03</u> mm dd yy	P/C/B F M L	Permanent #: /4	03-122085-106

Gender:	□ Male ☑ Female	Age: 5	Years	
Does the s	subject have any of the following at the treatment sites?			
I. DER	MATOLOGIC DISORDER	No	Yes	Don't Know
1.	Psoriasis?			
2.	Eczema?			
3.	Skin Cancer ?			
4.	Skin Allergies? Please specify:			
5.	Hives ?			
Does the	Subject have any of the following (present and past)?			4
II. OTE	ER MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.			
2.	Hepatitis ?			<u> </u>
3.	Heart and Vascular Disease? hbo			
4.	Liver Disease ?			<u> </u>
5.	Kidney Disease?			
6.	Tuberculosis?			
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8.	Cancer ?			
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.))?		
10.	Organ transplant?			
11.	Any other condition not listed? Please specify: HRT, Own;	etu l		
Is the su	bject taking any medication? If yes, please specify below:			
III. ME	DICATION	No	Yes	Don't Know
1.	Antibiotics, oral or systemic?	/_		
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3.	Heart Medication? Dovasc Oma Ixday			
4.	Insulin?			
5.	Other? Evista 60 ma (xday (HRT)		/0	
Comme	well but in 150mg and 1xday Well but in 150mg and 1xday Well but in 150mg and 1xday Canti	Joseph John	off 50	mg Yotab (Oinxield
i) mg vo Based or		1	alified for the	study.
			12/ 10 dd)3 yy

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: TV - 294

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	D7/21/03	P/C/B	Permanent#: 14	03-122085-106

			INCLUSION CRITERIA
Ch	neck one		
YES	N	0	Subject:
			1. Is 18 through 65 years?
			2. Has signed informed consent?
	•		3. Is healthy as evidenced by responses on DCF 1?
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?
V			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?
/			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?
/	·		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?
			11. Is willing to comply with all study protocol requirements?
			EXCLUSION CRITERIA
C	Check one		·
YES ·	NO	N/A	Subject:
			1. Is currently participating in another clinical study at this or any other facility?
			2. Has participated in any type of hand or arm wash study within the past 7 days?
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?
	/		4. Has artificial nails or nail tips?
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?
			6. Has eczema or psoriasis on their hands or wrists?
Female	Female	Male	 7. Is currently pregnant? □ Yes □ No Of child-bearing potential: □ Yes □ No □ Surgically Sterile, year □ Post-menopausal, year □ If of child bearing potential - β-HCG Test Results: □ negative □ positive 8. Is currently lactating?
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?
			10. Has another medical condition which in the opinion of the Investigator would preclude participation?
			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?
		2 Qua	SPX //\1/\2
)	gator's Sig		Oxu, R. Brays Date: 08, 10, 03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>W</u> - 295

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

	TENTO CAUCHAITA	21 (200) 001 (001)	CHARLE MEDICALIA	TI A CACIA	
Visit Code	Date	Subject Initials	Subject Screen #:	Study#	
Test Period	07/29/03 mm dd yy	P/L/B F M L	Permanent#:	03-122085-106	

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Eyes No If no, please indicate condition:								
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No If no, please explain:								
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	No .					
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	ete below) 🖾 No					
Based upon the above respon	ses, the subject is: ZQu	nalified 🗆 Not	Qualified to contin	ue on the study.				
Reasons for disqualifica	tion:	······································						
	·							
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS				
Date of Onset:	Date Reported	•	Date Resolve	ed:				
Describe condition:								
Was reaction related to treatme	ent? \square Not related \square	Possibly related	☐ Definitely related	Other (explain)				
Action Taken: None C	continued on study	Withdrawn from	the study Co	nsulted physician				
☐ Medicati	on taken (Complete belo	ow) []Hospitalized	i 🛘 Other (expla	in)				
Additional Comments:				***************************************				
	CON	COMITANT ME	EDICATION					
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)				
		1 1	1 1					
		1 1	1 1					
·		1 1	1 1	•				
Comments:								
Interviewer's Signature:	Tacy & Bord	rerdin "	Date: 07/2	9 / 03 dd yy				

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07 /29 / 03 mm dd yy	PLB FML	Permanent #:	03-122085-106

		ì	BASELIN	NE.				
LEFT HAND DILUTIONS				RIGHT HAND DILUTIONS				
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶		10 ⁻⁴	10 ⁻⁵	10-6		
TUTE	250	31_		WIZ	247	22		
MIZ	213	23		more	235	37		
CFU/mL2.5X10 ⁷ Counted by: 17-31-03				CFU/mL2.7x10	7 Counted by:	Ta 12.31.03		

LEFT HAND	•	WASH 1				RIGHT I	IAND
10-1	10 ⁻²	10-3	10⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10-4
TWO	MR	98	}(MI	TWIZ	136	14
nte	TUT	100	12	MTZ	TWIZ	131	1/
MI				MIT			
CFU/mL 9.9 x 10 4	Counte	ed by : <u>TO</u>	17:31:03	CFU/mL[.3 XID 5	Counted by	-7a	17.31.03

LEFT HAND			WASH 11			RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	10-4		
TATE	88	OLA	2	TATC	149	19	3		
TATE	135	15	1	TATE	157	20	2		
TNTC				TATE					
CFU/mL 1. 1x104	_ Coun	ated by: 545	17-31-03	CFU/mL 1.5 x 105	_ Counted by	y: 543	17-31-03		

* LA=Lab Accident, probable spreading error. SAS 7-31-03

Calculations by: JNB	108.01.03	Raw data reviewed by	SLH	18-6-03
Coloulations Verified by:	5As / Q.	- 1-03		······································

Calculations Verified by: <u>745</u> / <u>8-1-03</u>
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.
Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature:	Date:	8,11,03	
D' Will		mm dd yy	
V			

ata Conection Form (

HTR Study No.: 03-122085-106

FOLLOW-UP VISIT

Page No.: II - 297

Visit Code	Date	Subject Initials	Subject Screen #:	Study#	
Follow-up Visit	08/04/03 mm dd yy	$\frac{P/L/B}{FML}$	Permanent #: 14	03-122085-106	

Date Subject Entered the Study: O7/21/03 mm dd yy	Follow-Up Visit Date: <u> </u>
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? TYES Y NO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatment	procedure?
YES NO If yes, complete below	·
Comments:	
Medical Consultant's Signature:	S, 4,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>W - 298</u>

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

DEMOGRAM MCG/DEMONTOLOGICAL MGTORT TOXIL									
Visit Code	Date	Subject Initials	Subject Screen #:	Study#					
Subject Qualification	67,21,63 mm dd yy	$\frac{C'}{F}$ $\frac{R}{M}$ $\frac{C}{L}$	Permanent#:	03-122085-106					

Gender: D Male D Female	Age: <u>37</u>	Years	
Does the subject have any of the following at the treatment sites?			
I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis?		•	
2. Eczema?			
3. Skin Cancer?			
4. Skin Allergies? Please specify:	//		
5. Hives?			
Does the Subject have any of the following (present and past)?			
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.			
2. Hepatitis?			
3. Heart and Vascular Disease? hop			
4. Liver Disease?			
5. Kidney Disease?			
6. Tuberculosis?			
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8. Cancer?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?			
10. Organ transplant?			
11. Any other condition not listed? Please specify: Ondestero		/	
Is the subject taking any medication? If yes, please specify below:	lin		
III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic?			
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3. Heart Medication? Dovan 80 Mg Irday, Water pill 2	5 mg Ixdaun	سر.	
4. Insulin?			
5. Other? (ipital 10mg (xday (cholesterol)		<u></u>	
comments: Oxycontin 40mg axday (back pai	n)		
Based on the above medical history, the subject is:	Not qualifi	ed for the	study.
Interviewer's Signature: Jace & Muledia Date	: <u>07 / c</u>	2/ / C	<u>уу</u>
	-	-	

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>TV - 299</u>

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	07,21,03	C/K/J	Permanent#: 15	03-122085-106

			INCLUSION CRITERIA					
Ch	eck one							
YES	N	0	Subject:					
			1. Is 18 through 65 years?					
سن			2. Has signed informed consent?					
	3. Is healthy as evidenced by responses on DCF 1?							
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?					
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?					
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?					
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?					
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?					
			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?					
			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?					
			11. Is willing to comply with all study protocol requirements?					
			EXCLUSION CRITERIA					
C	heck one	.· .						
YES	NO	N/A	Subject:					
			1. Is currently participating in another clinical study at this or any other facility?					
			2. Has participated in any type of hand or arm wash study within the past 7 days?					
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?					
			4. Has artificial nails or nail tips?					
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
			6. Has eczema or psoriasis on their hands or wrists?					
Female	Female	Male	7. Is currently pregnant? ☐ Yes ☐ No Of child-bearing potential: ☐ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☐ negative ☐ positive 8. Is currently lactating?					
9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?								
		1.	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.					
		1	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?					
		₽ Qu	cation: Interviewer's Initials/Date: / 1/01/03					
Investi	gator's Sig	mature:	Ow R. Brass Date: 08 / 10 / 03 mm dd yy					

HTR Study No.: 03-122085-106
Page No.: X - 300

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

	HALLOCKERAL MARKET COLLEGE AND THE PROPERTY OF										
Visit Code	Date	Subject Initials	Subject Screen #:	Study#							
Test Period	07/29/03 mm dd yy	$\frac{C_{/}R_{/}J}{F_{M}L}$	Permanent #: 15	03-122085-106							

			·					
I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Eyes DNo If no, please indicate condition:								
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? EYes If no, please explain:								
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	Z No					
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) 🖄					
Based upon the above respon	ses, the subject is: 🛛 🔾 u	alified 🗆 Not 🤆	Qualified to contin	ue on the study.				
Reasons for disqualifica	tion:							
TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS								
Date of Onset:	Date Reported	•	Date Resolve	d:				
Describe condition:								
Was reaction related to treatment? ☐Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain) Action Taken: ☐None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician ☐ Medication taken (Complete below) ☐Hospitalized ☐ Other (explain) Additional Comments:								
		COMITANT ME						
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm/dd/yy	Indication (Reason for Taking)				
		1 1	/ /					
		1 1	1 1					
·		1 1	1 1					
Comments:			•					
Interviewer's Signature:	To E Rache		Date: <u>67 / 6</u>	09/03				

mm dd уу

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen#	Study#
07 /29 / 03 mm dd yy	C/R/J F M L	Permanent #:	03-122085-106

BASELINE							
LEFT HAND DILUTIONS				RIGH	IT HAND DILUT	TIONS	
10-4	10 ⁻⁵	10-6	[10-4	10 ⁻⁵	10 ⁻⁶	
MIZ	231	18		TUTC	250	30	
MIL	273.	24		MI	168	18	
CFU/mI2-4X10	Counted by:	17.31·03		CFU/mL2.2x10	Counted by:	16 17.31.03	

4 Not estimated due to countability of the place. The 7.31.03

LEFT HAND		WASH 1			RIGHT HAND		
10-1	10-2	10 ⁻³	10 ⁻⁴	10 ⁻ⁱ	10 ⁻²	10 ⁻³	10-4
MTC	MIZ	MIZ	63	TWT	TWTU	227	3/
STM	ME	MIZ	35	WTZ	MR	216	16
MR				THE			
CFU/mL49 x 10 ⁵	_ Count	ed by :	17.31.03	CFU/mL 2.3 × 10 5	Counted by	: 76	17.31.03

LEFT HAND		WASH 11				RIGHT HAND		
10-1	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10-2	10-3	10-4	
TUTE	Three	38	3	TATIC	TUTC	54	4	
THIC	mic	37	5	MC	TATE	29	3	
Trute				TATE				
CFU/mL3.8x1D4	Counte	ed by : £45	17-31-03	CFU/mL.4.2 X 10 4	Counted by	y: <u>E4J</u>	17-31-03	

Calculations by:	JNB	108.0	01.03	Raw data reviewed by _	SLH	18.6.03
Calculations Veri	ified by:	SAS	/ 8-	1-03		
*10-1 dilution is t						
Underlined value	s are used f	or calcula	tion of	CFU/mL		

TNTC - Too Numerous To Count

Investigator's Signature:	a. a Bul	Date:	08	10	103	
1	Un K. Shan	<u> </u>	mm	aa	уу	
		1 .				

Subject Initials ______ Subject #__

Study No.

Page No.

		ADVER	SE EV	ENTS					
Şymptom / Event	Onset Date E	nd Date	SAE ¹ S	everity	Action Taken	Outcome	elation- ship	investi Signatur	e/Date
Maculo	7-30-03	8/8/03	N	1	4/1)		4/2)	-deine	18-71-8
Entry Comment/Note:)	Wed Non- RC	other	2	2) Du	& &	st org	prisin	124	Initials
3-403 Fc	red red	ma	w	les	01 -	the.	boy	2)-21-U
of-	the ha	nds							Cy J
18/03 Hands	Clear	- U	we	d c	oritu	ion).	05 m	ia	gen"
1 time	on 7/31	103				0		0	· G
	Onset Date	End Data	SAE ¹	Severity	Action	Outcome	Relation-		ligator
Symptom / Event	Onset Date	End Date	Y/N	Seventy	Taken	Outcome	ship	Signate	ure/Date
Entry Comment/Note:									Initials
Date Comment/Note:							<u> </u>		initials
			-					······	
						\			
				•				•	
	•								
Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation ship		stigator ture/Date
Entry Comment/Note:						<u> </u>			Initials
				,,					
		•							
Note: Severity, Re		Outcome 2=Mod	e MU	ST be	determine 3=Se	ed by prin	icipal in	vestigat	or.
•••••	efinite	2=Pro	•			ssible		4=Unrel	ated

1=None

Action Taken:

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome:

1=Resolved w/o sequelae

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

1Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: 11-303

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Follow-up Visit	08/04/03 mm dd yy	C/R/J F M L	Permanent #: 15	03-122085-106

Date Subject Entered the Study: <u>07, 21, 03</u> mm dd yy	Follow-Up Visit Date: OB, O4, O3 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? YES INO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s Four ref wecceles on Onset 7-30-03	backs of hereby
Comments:	
Has the subject had any health related issues since the treatmen	at procedure?
☐ YES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	B Date Mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07/15/03 mm dd yy	1 / - /S F M L	Permanent #:	03-122085-106

	Qualification mm dd yy F M L	16	-122085-100			
Gender:	☐ Male	Age: 60	Years			
Does the s	ubject have any of the following at the treatment sites?					
L DERI	MATOLOGIC DISORDER	No	Yes	Don't Know		
1.	Psoriasis?		•			
2.	Eczema?	V				
3.	Skin Cancer?	V				
4.	Skin Allergies? Please specify:	V,				
5.	Hives ?	V				
Does the	Subject have any of the following (present and past)?					
п. отн	ER MEDICAL INFORMATION	No/	Yes	Don't Know		
1.	Allergies.? Please specify.			WifoM		
2.	Hepatitis?	——————————————————————————————————————		 		
3.	Heart and Vascular Disease?	1//				
4.	Liver Disease ?					
5.	Kidney Disease ?		 	 		
6.	Tuberculosis ?		 	 		
7.	Diabetes? Controlled? Diet [] Oral [] Insulin []					
8.	Cancer?		 			
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, et	c)?	∤	 		
10.	Organ transplant?	5.7.	/			
11.	Any other condition not listed? Please specify:			 		
	bject taking any medication? If yes, please specify below:			4		
		No	Yes	Don't		
III. ME	DICATION	No	1 65	Know		
1.	Antibiotics, oral or systemic ?		<u> </u>			
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	- V/	,			
3.	Heart Medication ?	V/				
4.	Insulin ?		1			
5.	Other ?	\\\\\\\	1			
Comme	nts:					
				•		
	de de maioritaire de maioritaire de l'Occident	w [] NT=4 ====12	and for the	atu da		
Based or	the above medical history, the subject is: Qualified of	A7	ied for the	oiday.		
Interviev	ver's Signature:	Date: 0 /	15,0	<u> </u>		
	Janu Buseneyer mm dd yy					

HTR Study No.: 03-122085-106
Page No.: TV - 305

		INCLUS	ION / EXCLUSION	FORM	Page No.:
	Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	Subject Qualification	07,15,03 mm dd yy	L,-,S f m 1	Permanent#:	03-122085-106
		INC	CLUSION CRITERI	A	
n				•	

		INCLUSION CRITERIA							
Ch	eck one	·							
YES	NO	Subject:							
	//	1. Is 18 through 65 years?							
		2. Has signed informed consent?							
V		3. Is healthy as evidenced by responses on DCF 1?							
$\underline{\hspace{1em}} V$	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?								
V	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?								
/	/	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?							
		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?							
V		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?							
V		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?							
V		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?							
V		11. Is willing to comply with all study protocol requirements?							
		EXCLUSION CRITERIA							
С	Check one	•							
YES	NO / N/A	Subject:							
	V	1. Is currently participating in another clinical study at this or any other facility?							
	VX.	2. Has participated in any type of hand or arm wash study within the past 7 days?							
	VX	3. Has cuts, lesions, or other skin disorders on their hands or wrists?							
	1	4. Has artificial nails or nail tips?							
		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?							
		6. Has eczema or psoriasis on their hands or wrists?							
Female	Female Male	7. Is currently pregnant? □ Yes ② No Of child-bearing potential: □ Yes ② No □ Surgically Sterile, year □ Post-menopausal, year □ If of child bearing potential - β-HCG Test Results: □ negative □ positive 8. Is currently lactating?							
		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?							
	V	10. Has another medical condition which in the opinion of the Investigator would preclude participation?							
	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.								
		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?							
		ogic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: alified							
Keas	ous for disqualin								
Investi	gator's Signature:	Date: 08/10/03							

HTR Study No.: 03-122085-106
Page No.: W - 306

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

·	A TRACTICAL TELEVISION OF THE PROPERTY OF THE						
Visit Code	Date	Subject Initials	Subject Screen #:	Study#			
Test Period	07/23/03 mm dd yy	<u>L,-,S</u> F M L	Permanent #: 16	03-122085-106			

I. Is skin on subject's hands a If no, please indicate co	nd wrists still free of der	-	•	lisorders? Pres 🗆 No		
II. Has subject used non-antib	pacterial soap and follow		=	es □No		
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	No			
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) ENo			
Based upon the above respon	ses, the subject is: 🗷 🗓	alified Not	Qualified to contin	ue on the study.		
Reasons for disqualifica	ation:					
TO BE C	COMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS		
Date of Onset:	Date of Onset: Date Reported: Date Resolved:					
Describe condition:						
☐ Medicat	Continued on study	Withdrawn from	the study Co	nsulted physician in)		
Additional Comments:						
Medication	1	COMITANT MI Start Date	Stop Date	Indication		
(Oral or Systemic)	Total Daily Dose	mm/dd/yy	mm/dd/yy	(Reason for Taking)		
		1 1	1 1	·		
		1 1	1 1			
Comments:			,			
· Interviewer's Signature:	- P 4-5	D. 2	Date: 67 /	23 / 03		

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date Subject Ini		Subject Screen #	Study#
07 /23 /03 mm dd yy	$\frac{L - S}{F \cdot M}$	Permanent #:	03-122085-106

	BASELINE								
LEI	T HAND DILUTI	ONS		RIGI	IT HAND DILUT	ONS			
10 ⁻⁴	10-5	10 ⁻⁶		10 ⁻⁴	10 ⁻⁵	10 ⁻⁶			
TNTC	151	18—		TNTC	209	25_			
TNTC	194_	25_		TNTC	220	T8			
CFU/mL 1.9 x	Counted by:	NB 107.25.03		CFU/mL2.1x	O Counted by: J	NB 107.25.03			

LEFT HAND			W.	ASH 1		RIGHT I	HAND
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4
TNTC	TNTC	159	· 14	TNTC	TNTC	121	29
TNTC	TATC	201	+ 20	TNTC	TNTC	T72	24_
TNTC				TNTC			
CFU/mL 1.8 × 10.5	Count	ted by :	1B 107.25.03	CFU/mL 2.0 × 10 5	Counted by	: JNB	107.25:03

LEFT HAND			WA	ASH 11	RIGHT HAND			
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4	
TUT	アルケて	フユ	-5	TNTC	TUT	90	- 12	
TNTC	TNTC	75	- (0	TNTC	TNTC	59	_ '4	
TNTC				TNTC				
CFU/mL 7.6 × 10 4	_ Counte	d by : <u>SC</u>	17/25/03	CFU/mL 7.4 × 10 4	_ Counted by	: 508	7/25/03	

Calculations by: 1 / 7 26 · 03 Raw data reviewed by Calculations Verified by: 1 / 07 · 29 · 03	arb	18.1.03
Calculations Verified by: JNB /07-29-03		
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.		
Underlined values are used for calculation of CFU/mL	•	
TNTC - Too Numerous To Count		

Investigator's Signature:	Smill	Date: <u>6 11(10 3</u> mm dd yy

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 308

Visit Code		Date		Subject Initials		Subject Initials Subject Screen #:		Study#
Follow-up Visit	<u>07/</u>	26/	03 w	<u>_</u>	/ <u></u>	<u>/S</u>	Permanent#:	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u>	Follow-Up Visit Date: 07/28/03
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, of that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
TYES NO If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/se	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatment	procedure?
TYES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Date 7,28,03 mm dd yy

HTR Study No.: 03-122085-106
Page No. <u>JV - 3</u>09

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 125	Study#
Subject Qualification	07115103 mm dd yy	K/L/D F M L	Permanent #: 17	03-122085-106

	TOY OGIG PROPER	NT.	37	Don't
	ATOLOGIC DISORDER	No	Yes	Know
	Psoriasis ?	- //		
	Eczema ?	V/		
	Skin Cancer ?			
	Skin Allergies? Please specify:			
5.	Hives ?			
Does the S	ubject have any of the following (present and past)?			
II. OTHE	R MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.	1//		
	Hepatitis ?	VI		
3.	Heart and Vascular Disease?	V		
4,	Liver Disease ?			
5.	Kidney Disease ?			
6.	Tuberculosis?			
7.	Diabetes ? Controlled? Diet [] Oral [] Insulin []			
8.	Cancer?	V,		
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	V/		
10.	Organ transplant?			
11.	Any other condition not listed? Please specify:	1/		
Is the sub	ject taking any medication? If yes, please specify below:	V		
III. MED	ICATION	No /	Yes	Don't Knov
1.	Antibiotics, oral or systemic?	1/		
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	V		
3.	Heart Medication ?			
4.	Insulin?			
۳۰.	Other?	V		

Data Collection Form 2 INCLUSION / EXCLUSION FORM

Subject Initials

Visit Code

Subject

Date

HTR Study No.: 03-122085-106 Page No.: <u>TV - 310</u> Subject Screen #: 125 Study # Permanent #:

03-122085-106

` }			Qualif	ication	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$					
<u> </u>					INCLUSION CRITERIA					
	Che	ck one								
	YES	N	0	Subject:						
_	1. Is 18 through 65 years?									
_	2. Has signed informed consent?									
	3. Is healthy as evidenced by responses on DCF 1?									
_	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?									
_	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?									
	V	1_			rilling to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, wering, and handwashing during the entire study?					
		4		7. Is w	rilling to refrain from using anti-dandruff shampoo during the entire study?					
	V			liqui	rilling to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing sids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a sician for an intercurrent illness?					
	V				villing to refrain from using topical steroids during the entire study, unless prescribed by a sician for an intercurrent illness?					
	V				villing to refrain from using topical or systemic antibiotic medication during the entire study, ess prescribed by a physician for an intercurrent illness?					
Γ	V			11. Is w	willing to comply with all study protocol requirements?					
Γ					EXCLUSION CRITERIA					
	CI	neck one								
)_	YES	NO	N/A	Subject:						
_		-V,	<u>/</u>	<u> </u>	currently participating in another clinical study at this or any other facility?					
_		/	}		s participated in any type of hand or arm wash study within the past 7 days?					
L		_/			s cuts, lesions, or other skin disorders on their hands or wrists?					
F		_/_	1		as artificial nails or nail tips?					
-		-V,	 		as soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
-		V	 		s eczema or psoriasis on their hands or wrists? currently pregnant? Yes No Of child-bearing potential: Yes No					
I	emale	Female	Male		☐ Surgically Sterile, year ☐ Post-menopausal, year					
_			X-		of child bearing potential - β-HCG Test Results: V negative positive 7/23/03					
		V		0. 15	currently lactating?					
		V		hej	as been medically diagnosed as having a medical condition such as: diabetes, patitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus ythematosus, thyroiditis or rheumatoid arthritis?					
		V		pre	as another medical condition which in the opinion of the Investigator would eclude participation?					
		V		W	as any responsibility for care of children under age 3, or has responsibilities for diapering, care of counds, intravenous management or other bed-ridden related care roles.					
, [1/		12. Ha	as a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?					
	Based	l upon de	rmatolo		tion and the information contained in Data Collection Forms 1 and 2, the subject is: One Qualified for participation in this study.					
	Reaso	ns for di	•		Interviewer's Initials/Date: TNB /07.15.03					
	Investig	ator's Si	gnature:		am R. Brack Date: 08/10/03 mm dd yy					

HTR Study No.: 03-122085-106
Page No.: 12-31

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: 125	Study#
Test Period	07/23/03 mm dd yy	K/L/D F M L	Permanent#:	03-122085-106

I. Is skin on subject's hands a If no, please indicate co		•	*	i i
II. Has subject used non-antib				
III. Has subject been ill since t	he last visit? □Yes (Cor	mplete below)	No	
IV. Has subject used any new	oral or topical medicatio	n? □Yes (Comple	te below) 📶 No	
Based upon the above respon	ses, the subject is: 🖽 🔾 1	ialified 🗆 Not	Qualified to contin	ue on the study.
Reasons for disqualifica	ation:	····		
	·			
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS
Date of Onset:	Date Reported		Date Resolve	ed:
Describe condition:				
	Continued on study	Withdrawn from	the study Co	nsulted physician in)
	CON	COMITANT MI	DICATION	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		1 1	1 1	
		1 1	/ /	
		1 1	1 1	
Comments:				
· Interviewer's Signature:	1 4	. 1		23 / 63

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

		, g	
Test Date	Subject Initials	Subject Screen # 125	Study#
07/23/03 mm dd yy	K/L/D F. M L	Permanent #:	03-122085-106

BASELINE							
LEFT	HAND DILUTION	ONS	RIGHT	RIGHT HAND DILUTIONS			
10-4	10-5	10 ⁻⁶	10-4	10-5	10-6		
TNTC	180	6	TNTC	177	(0		
TUTC	788	12	TNTC	138	14		
CFU/mL1.8×10	Counted by:	B17/26/2	CFU/mL/.6×10	Counted by:	20_17/25/03		

LEFT HAND			W.	ASH 1		RIGHT H	AND
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	10-4
TUTC	TUTC	72	- 5	TNTC	TUTC	42	- X
TNTC	TNTC	53	7	TNTC	TUTC	58	X
TNTC				TUTC			-
CFU/mL 6.2×104	Counte	d by : <u>SC</u> B	1795/63	CFU/mL 5.2 x /3 4	Counted by:	593 /	7/25/03.

LEFT HAND		WASH 11					
10-1	10-2	10 ⁻³	10-4	10 ⁻¹ ·	10-2	10-3	10-4
TNTC	TUTC	89	8	TNTC	TNYC	160	- 17
TNTC	TNTC	87	14	TNTC	TUTC	137	18
TNTC				TNTC			
CFU/mL8.8 × 104	Counte	d by : <u>88</u> 8	17/05/03	CFU/mL 1.5 × 10 5	Counted by	: 885	17/05/63.

Calculations by:	als	18.1.03
Calculations Verified by: JNB /07-29:03		
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.		
Underlined values are used for calculation of CFU/mL	•	
TAITC Too Name on the Count		

Investigator's Signature:	Date: <u>S / // 10 3</u>

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: II - 313

Visit Code		Date		Subjec	et Initi	als	Subject Screen	# 5	Study #
Follow-up Visit	07/ H	28 /	03 yy	K F	/ <u>L</u>		Permanent #:	17	03-122085-106

Date Subject Entered the Study: O7 / 15 / 03 mm dd yy	Follow-Up Visit Date: <u>07 / 28/03</u> mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? TYES Y NO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatmen	t procedure?
Comments:	
Medical Consultant's Signature:	Date 7,28,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>W - 314</u>

Data Collection Form 1

DEMOCRAPHICS/DERMATOLOGICAL/MEDICAL EIGTODY FORM

Subject Qualification $\frac{57/5}{\text{mm}} \frac{3}{\text{dd}} \frac{1}{\text{vy}} \frac{1}{\text{F}} \frac{1}{\text{M}} \frac{1}{\text{L}}$ Permanent #: 18 03-122085-106	Visit Code	Date	Subject Initials	Subject Screen #:	Study #
		07/15/03 mm dd yy	Y/L/W F M L	Permanent#: 18	03-122085-106

Gender: 🗆 Male	Female .	Age: <u>4</u>	Years			
oes the subject have any of the	following at the treatment sites?					
I. DERMATOLOGIC DISO	RDER	No	Yes	Don't Know		
1. Psoriasis?						
2. Eczema?						
3. Skin Cancer?		- U				
4. Skin Allergies? Pleas	e specify:					
5. Hives?						
Does the Subject have any of th	e following (present and past)?					
II. OTHER MEDICAL INFO	DRMATION	No ·	Yes	Don't Know		
1. Allergies.? Please spe	ecify.					
2. Hepatitis?						
3. Heart and Vascular D	isease?					
4. Liver Disease ?						
5. Kidney Disease?						
6. Tuberculosis?						
7. Diabetes? Controll						
8. Cancer?						
9. Auto-immune disease						
10. Organ transplant?						
11. Any other condition r	not listed? Please specify: white action	ue thurs d.	<i>\</i>			
	ation? If yes, please specify below:	ligrainis, acid	reflux,			
III. MEDICATION		No	Yes	Don't Know		
1. Antibiotics, oral or sy						
	ACTH, Anti-reaction Drugs?					
3. Heart Medication?						
4. Insulin?		ractive				
5. Other? Sunthr	oid 0.112 mg Irday Cthy	roid)				
wellbut	10mg 1x day (anti-depressa rin 150mg 1xday Conti-de	nt, & migrainus)	5/03 d 30 m	a Ixday(a		
Wadded as yer	subject 7/16/03 gh			1,1		
Based on the above medical hist	ory, the subject is:	or 🗆 Not qual	ified for the	study. (hid		
Interviewer's Signature:	o Andred.	Date:	15,0	3_		

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: TV - 315

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07/15/63 mm dd vy	V,L,W	Permanent #:	03-122085-106

INCLUSION CRITERIA									
Ch	eck one								
YES	N	0	Subject:						
		1. Is 18 through 65 years?							
-			2. Has signed informed consent?						
			3. Is healthy as evidenced by responses on DCF 1?						
0			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?						
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?						
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?						
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?						
J	/		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?						
			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?						
/		-	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?						
			11. Is willing to comply with all study protocol requirements?						
			EXCLUSION CRITERIA						
Check one									
YES	NO	N/A	Subject:						
	1. Is currently participating in another clinical study at this or any other facility?								
	2. Has participated in any type of hand or arm wash study within the past 7 days?								
	3. Has cuts, lesions, or other skin disorders on their hands or wrists?								
	4. Has artificial nails or nail tips?								
	1		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?						
			6. Has eczema or psoriasis on their hands or wrists?						
Female	Female	Male	Male 7. Is currently pregnant? \(\text{ Yes } \otin \text{ No } \) Of child-bearing potential: \(\text{ Yes } \otin \text{ No } \) \(\text{ Surgically Sterile, year \(\text{ Post-menopausal, year } \) \(\text{ If of child bearing potential - β-HCG Test Results: \(\text{ No } \) \(\text{ No } \) \(\text{ Post-menopausal, year } \) \(\text{ Post-menopausal, year } \) \(\text{ No } \) \(\text{ If of child bearing potential - β-HCG Test Results: \(\text{ No } \) \(\text{ No } \) \(\text{ Post-menopausal, year } \) \(\text{ No } \) \(\text{ Post-menopausal, year } \) \(\text{ No } \) \(\text{ No } \) \(\text{ If of child bearing potential - β-HCG Test Results: \(\text{ No } \) \(\text{ No } \) \(\text{ No } \) \(\text{ Post-menopausal, year } \) \(\text{ No } \) \(\text{ No } \) \(\text{ No } \) \(\text{ No } \) \(\text{ If of child bearing potential - β-HCG Test Results: \(\text{ No } \) \(\te						
	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would								
	preclude participation? 11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of								
	/		wounds, intravenous management or other bed-ridden related care roles.						
		<u></u>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?						
1		☑ Qua	3PA ////X						
)[gator's Sig		aw R. Brand Date: 08,10,03 mm dd yy						

HTR Study No.: 03-122085-106
Page No.: XX - 316

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

		DI (2007 - 01 (0 01 (MARKIT MUDICATIO	IV I OIGH
Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	07/23/03 mm dd yy	V/Z/W F M L	Permanent#:	03-122085-106

I. Is skin on subject's hands a	and wrists still free of der		•	disorders? Pres No
II. Has subject used non-antitude If no, please explain:	pacterial soap and follow			
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	No No	
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	ete below) ANo	
Based upon the above respon	ises, the subject is: 🗷 🕏	alified Not	Qualified to contin	nue on the study.
Reasons for disqualification	ation:			
TO BE C	COMPLETED IF SUBJ	ECT HAS AN I	NTERCURRENT I	LLNESS
Date of Onset:	Date Reported	•	Date Resolve	ed:
Describe condition:			•	
Was reaction related to treatm	ent? [Not related] I	Possibly related	☐ Definitely related	l 🗆 Other (explain)
Action Taken: None	Continued on study	Withdrawn from	the study 🛮 Co	nsulted physician
☐ Medicat	ion taken (Complete belo	ow) []Hospitalized	i 🛘 Other (expla	in) .
Additional Comments:		the control of the state of the		
	CON	COMITANT ME	DICATION	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm/dd/yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		1 1	1 1	
		1 1	1 1	
		1 1	/ /	
Comments:				

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	$\frac{V/L/W}{F. M L}$	Permanent #:	03-122085-106

		BAS	SELINE		
LEF	T HAND DILUT	IONS	RIGI	HT HAND DILUT	IONS
10-4	10-5	10 ⁻⁶	10-4	10-5	10-6
TATC	115_	16	TNTC	145-	14
TNTC	127	14	TNTC	134	12
CFUML 18x	Counted by:	NB 107.25.03	CFU/mL /- 47/	O Counted by:	JNB /07.25.03

(2) Tb 7.29.03

LEFT HAND			W.	ASH 1	······································	RIGHT	HAND
10-1	10-2	10-3	10-4	10 ⁻¹	10-2	10-3	10-4
TNTC	TNTC	TNTC	42	TNTC	TNTC	150	2.2
TNTC	TNTC	TNTC	42	TNTC	TNTC	765	_23
TNTC				TNTC			
CFU/mL 4.2×105	Count	ted by : JN	3 107.25.43	CFU/mL 1.6 x 10 5	Counted by	: JNB	107.2503

LEFT HAND			W.	ASH 11		RIGHT F	IAND
10 ⁻¹	10-2	10-3	10 ⁻⁴	10 ⁻¹	10-2	10-3	10-4
TNTC	TNTC	176	19	TNTC	TNTC	177	21
TNTC	TNTC	177	. 20	TNR	TNTC	144	19
TNTC				TUTC			····
CFU/mL 1.8 × 105	Counted	by: _ 0 %	17.25.03	CFU/mL 1.6×105	_ Counted by :	_ an	7.25.0

Calculations by: To /2.36.63 Raw data reviewed by Calculations Verified by: JNB /07.29.03	allo	/	8.1.03
Calculations Verified by: JNB /07.29.03			
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.			
Underlined values are used for calculation of CFU/mL			
TNTC - Too Numerous To Count			

Investigator's Signature:	Sall		Date:	2	111	103	
No.	TUNCO	/		mm	aa	уу	
	Ì	ζ					

			Data	Collec	ction For	n 5A				
Subject Initials	VLW	s	ubject#_		8	•	Study N Page No		-12208 3 1	
			ATOXATRA	ימר קונט ו	TIDNING		i age iv	·		
			ADVER		VENIS					
Symptom / Event	c	Onset Date	End Date	SAE ¹	Severity	Action Taken	Outcome	Relation- ship	Invest Signatu	
ured bumps		1/24/03	9/14/03	N		40	1	46)	Lin	n 6-21
Entry Date Comment/Note:	1) Used	Non-Px	. Neorb	ostra	(2)	elto	test	regar	esuro.	Phitials
7/25/13 red S	HIMA	NOW	both	Sh	and	ม เกก	d sin	ista		an
1108pt	WIL	PM.	lumi	21).	9,	11. 13	heen	درور		0
1/4/03 Hand	^ J	MINT	0	OAH		MOR	Y W WY	· ·		080
11000	nt v	min 8	1+ (lere	n~1 7	1041n=	- 8/1	カクス		2,0
as me	dod	Curre		U	7.4.1	12-10-	1			<u> </u>
Symptom / Ever	nt	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship		stigator :ure/Date
Entry Comment/Note	:									Initials
·				·					•	
						······································				
		,		1 1				1		
. Symptom / Eve	nt	Onset Date	e End Date	SAE'	Severity	Action Taken	Outcome	Relation- ship		stigator iture/Date
Entry Comment/Not	e:									Initial
										•
			**************************************		······································					
			*		**************************************	·				
										
Note: Severity, F Severity: 1=	Relation: Mild	ship and		e MU derate	ST be c	letermine 3=Se		cipal inv	estigat	or.
	Definite		2=Pro				ssible		4=Unrel	lated
•	=None		2=Rx	Therap	ру .	3=Di	scontinued	Study	4=Othe	r (specify

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

Outcome:

1=Resolved w/o

sequelae

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IV - 319

Date Subject Entered the Study:	Follow-Up Visit Date:
<u>07, 15, 03</u>	07,28,03
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, of that may be indicative of a skin infection? YES INO If yes, complete below: Clinical Observations: (Include date of onset and descriptions/set) Six May Aparalles complete below:	everity/locations, etc.) Levels ond wrists eprocedure?
	•
Medical Consultant's Signature:	Date 7,28,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: <u>IV - 320</u>

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	$\frac{07/15/03}{\text{mm}}$	$\frac{\sum_{i} C_{i} S}{F M L}$	Permanent#: 19	03-122085-106

Gender:	☐ Male Female .	Age: <u>4</u>	3 Years	
Does the	subject have any of the following at the treatment sites?			
I. DEF	RMATOLOGIC DISORDER	No	Yes	Don't Know
1.	Psoriasis ?		·	
2.	Eczema?	1		
3.	Skin Cancer ?		<u> </u>	
4.	Skin Allergies? Please specify:			
5.	Hives ?			
Does the	e Subject have any of the following (present and past)?			•
п. от	HER MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.			
2.	Hepatitis ?	/		
3.	Heart and Vascular Disease?	1		
4,	Liver Disease ?			•
5.	Kidney Disease ?			
6.	Tuberculosis ?			
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8.	Cancer ?			
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	1		
10.	Organ transplant ?			
11.	Any other condition not listed? Please specify: back pain, dupre	SSM	1	
Is the s	ubject taking any medication? If yes, please specify below: Sinus			
nı. Mı	EDICATION	No	Yes	Don't Know
1.	Antibiotics, oral or systemic?	/		
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	V		
3.	Heart Medication ?			
4.	Insulin ?	1		
5.	Other? Paxil 50mg CR taken Ixday (dupressia	4)		
	(backpain) Darvocet NIOO mg taken asverded, Rotens: Ambien O 25 mg taken as needed (sleep) Adoran 25 mg taken as needed (sinus)	axin 7	50mg-	taken as i (back
Comm	xzanax 0.25 mg taken as needed (nerves		needed	(tension
	MOTOR SSMON Taken as needed (Nerves DSCB7/15/03 Feuricet 750mg to in the above medical history, the subject is:	ken when	needed for the s	

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: TV - 32

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	67/15/03 mm dd yy	DILIS f m 1	Permanent#:	03-122085-106

			INCLUSION CRITERIA				
	heck one		·				
YES	N	<u>O</u>	Subject:				
			1. Is 18 through 65 years?				
س			2. Has signed informed consent?				
			3. Is healthy as evidenced by responses on DCF 1?				
/			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?				
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?				
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?				
	-		7. Is willing to refrain from using anti-dandruff shampoo during the entire study?				
./			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?				
			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?				
ر ر	.`		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?				
/			11. Is willing to comply with all study protocol requirements?				
			EXCLUSION CRITERIA				
	Check one						
YES	NO	N/A	Subject:				
	/		1. Is currently participating in another clinical study at this or any other facility?				
			2. Has participated in any type of hand or arm wash study within the past 7 days?				
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?				
			4. Has artificial nails or nail tips?				
	//		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?				
	1		6. Has eczema or psoriasis on their hands or wrists?				
Female	Female	Male	7. Is currently pregnant? ☐ Yes ⋈ No Of child-bearing potential; ☑ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☑ negative ☐ positive 7/23/03 086				
	1		8. Is currently lactating?				
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?				
	/		10. Has another medical condition which in the opinion of the Investigator would preclude participation?				
	1 /,		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.				
	/_	<u> </u>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?				
		Qua	$\mathcal{O}_{\mathcal{L}}$				
Reas	ons for dis	qualific	ation: Interviewer's Initials/Date:/ ///5/03				
Investigator's Signature: Out R. Brack Date: 08 / 10 / 23 mm dd yy							

HTR Study No.: 03-122085-106
Page No.: W - 322

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	07/23/03 mm dd yy	2/1/5 F M L	Permanent#:	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Pyes DNo If no, please indicate condition:							
-	II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? EYes No If no, please explain:						
III. Has subject been ill since the	ne last visit? Yes (Cor	nplete below)	⊉No				
IV. Has subject used any new o	oral or topical medication	n? □Yes (Comple	te below)				
Based upon the above respon	ses, the subject is: 🗷 🔾 u	ialified Not	Qualified to contin	ue on the study.			
Reasons for disqualifica	tion:						
	·						
TO BE C	OMPLETED IF SUBJ	ECT HAS AN II	TERCURRENT II	LLNESS			
Date of Onset:	Date Reported	•	Date Resolve	ed:			
Describe condition:			•				
Was reaction related to treatme	ent? 🗆 Not related 🗀 I	Possibly related	☐ Definitely related	Other (explain)			
Action Taken: None C	ontinued on study	Withdrawn from	the study Cor	nsulted physician			
☐ Medicati	on taken (Complete belo	ow) [Hospitalized	Other (expla	in)			
Additional Comments:	**************************************						
	CON	COMITANT ME	DICATION				
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)			
		`1 1	, ,				
		1 1	/ /				
-		/ /	/ /				
Comments:							
Interviewer's Signature: Ro	Interviewer's Signature: Betty M. Conover Date: 07 / 23 / 03						

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#	
07/23/03 mm dd yy	D/ L/5 F. M L	Permanent#:	03-122085-106	

		BASE	LINE		
LEFT	HAND DILUTIO	NS	RIGHT	HAND DILUTIO	ONS
10-4	10 ⁻⁵	10-6	10-4	10 ⁻⁵	10-6
TNTC	140	24_	TNTC	230	21
TNTC	10 Stell	25	TNTC	759	25
CFU/mL_22×10	Counted by:	ed 7 25 63	CFU/mL.2.1 X 10	Counted by: S	B17/25/03

(1) Did not estimatedue to plate countability. Sel 1/05/03

LEFT HAND			W.	ASH 1		RIGHT H	AND
10 ⁻¹ .	10 ⁻²	10-3	10-4	10 ⁻¹	10 ⁻²	10 ⁻³	10-4
TATC	TNTC	114	13	TNTC	TNTC	TUTC	40
TNTC	TNTC	78	11	TNTC	TNTC	TNTC	-40
TN7C.				TNTC			
CFU/mL 9.6×104	Counte	d by : <u>S</u>	17/25/03	CFU/mL 4-0 x 10 5	Counted by	: Seb	17/25/03

LEFT HAND	EFT HAND WASH 11 RIGHT HAND					IAND	
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³	10 ⁻⁴
TNTC	TNTC	109	7	TNTC	TNTC	188	- 19
TNTC	TNTC	118	, 7	TNTC	TUTC	154	190
TNTC				TNTC			
CFU/mL 1.1 X 10.5	Counte	d by : _SP	योक्सिय	CFU/mL 1.7 × 10 5	Counted by	:50b	7/25/03.

Calculations by: TU / 7-26-03 Raw data reviewed by Calculations Verified by: JNB /07-29-03	alb 18.1.03				
Calculations Verified by: JNB /07.29.03					
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.					
Underlined values are used for calculation of CFU/mL					
TNTC – Too Numerous To Count					

Investigator's Signature:		Date:	8	, 10	103	
I have			mm	dd	УУ	
	V					

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106
Page No.: 17-324

Visit Code	Date	Subject Initials	Subject Screen #: 128	Study #
Follow-up Visit	07/28/03 mm dd yy	D/L/S F M L	Permanent #: 19	03-122085-106

Date Subject Entered the Study: 07/15/03	Follow-Up Visit Date: 07, 28,03
mm dd yy	3.3
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? TYES NO If yes, complete below:	
	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatmen	t procedure?
☐ YES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	Date
Lang trues upo	7 128103 mm dd yy